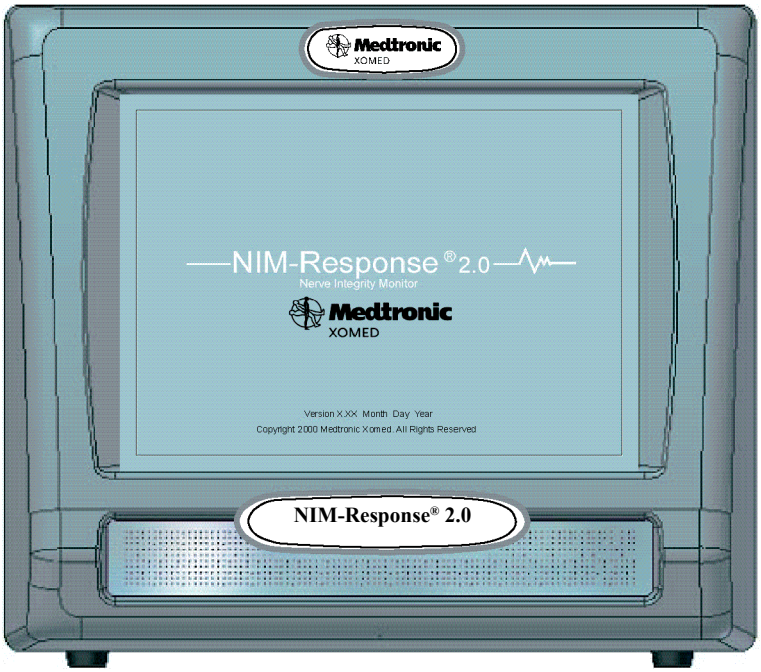
# NIM-Response® 2.0

## Nerve Integrity Monitor




# USER'S GUIDE

**Language Order**
**EN/SV/DA/FI**
**Rx Only**

NIM-Response® 2.0 Helpline
1-800-874-5797
For Questions and Service

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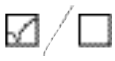
## Explanation of Symbols Used in the Labeling

Power Off / Power On

Radio Button
Select / Deselect


Check Box
Select / Deselect

Exit Pop-Up Window

Patient Cable

Input / Output

Printer Out

Audio Out


Monopolar Stimulus Probe
(Cathode)

Tone Monitoring Screen
Control - On

Equipotential

RF Transmitter (Interference may occur)

Type BF Applied Part

Volume

Help

Fuse

CE Mark Per MDD 93/42/EEC

Headphone out

Bipolar Stimulator Probe

Monopolar Stimulus Return
(Anode)

Voice Monitoring Screen
Control - On

This port is for future use only

IP21

Indication of the degree of protection of the enclosure:
1st Number: 2 – protects against fingers touching hazardous parts 2nd Number: 1 – equipment is minimally protected from dripping.

# 1.0 CUSTOMER SERVICE INFORMATION

**U.S. Customer Service Contact Information**
General customer service and technical support are available toll-free:
800-874-5797 or 904-296-9600
Monday - Friday: 8:00 AM – 6:00 PM E.S.T.
www.xomed.com

**Microelectronics Repair**
Technical Support:
800-872-9877
904-296-6448 (FAX)
Monday - Friday 8:00 AM – 5:00 PM E.S.T.
www.xomed.com

**Return Address:**
Medtronic Xomed, Inc.
6743 Southpoint Drive North
Jacksonville, FL 32216-0980 USA
Attn.: Repair Department

**Customer Service Information**
For further information regarding the use of this product or to report any problems, please contact Medtronic Xomed using the appropriate information provided on the blue and white contact information card packaged with each device; or contact your local distributor.

**The NIM Helpline.**
Should you need immediate help with a technical question or guidance through the appropriate protocol, just call the NIM Help Line at 1-800-874-5797.

**Note:** When contacting our Customer Service and Technical Support, please have the appropriate product number, product serial number, date of purchase, and nature of inquiry available.

Product Number: _____

Serial Number: _____

Date of Purchase:_____

# 2.0 INTRODUCTION

## 2.1 Device Description

The NIM-Response® 2.0 is a four-channel EMG monitor for intraoperative use during surgeries in which a motor nerve is at risk due to unintentional manipulation. The NIM-Response® 2.0 records electromyographic (EMG) activity from muscles innervated by the affected nerve. The monitor will assist early nerve identification by providing the surgeon with a tool to help locate and identify the particular nerve at risk within the surgical field. It will continuously monitor EMG activity from the muscles innervated by the nerve at risk to minimize trauma by alerting the surgeon when a particular nerve has been activated.

## 2.2 Indications for Use

This device is intended for use in surgical procedures for patient-connected intraoperative nerve monitoring, i.e. assisting the surgeon in locating and mapping motor nerves through the use of electromyographic (EMG) signals and electrical stimulus of nerves.

This device is indicated for locating and identifying cranial and peripheral motor nerves during surgery.

## 2.3 Contraindications

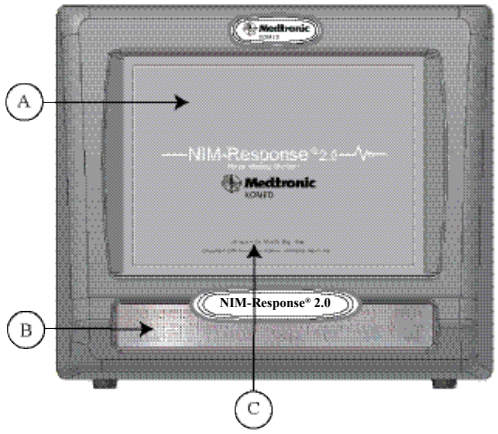
The use of paralyzing anesthetic agents will significantly reduce, if not completely eliminate, EMG responses to direct or passive nerve stimulation. Whenever nerve paralysis is suspected, consult an anesthesiologist.

## 2.4 Unpacking the NIM-Response® 2.0

When you unpack the NIM-Response® 2.0, save the cartons and packing material in which your monitor arrived. If the instrument is to be shipped from one location to another, the custom designed shipping package will provide the best protection.

When the box is unpacked, check off the contents of the box against the items listed on the packing slip. If the contents are incomplete, or if there is damage, notify MEDTRONIC XOMED Customer Service. If the shipping container is damaged, or the cushioning material shows signs of stress, notify the carrier as well. Keep the shipping materials for carrier inspection.

## 2.5 The Front Panel



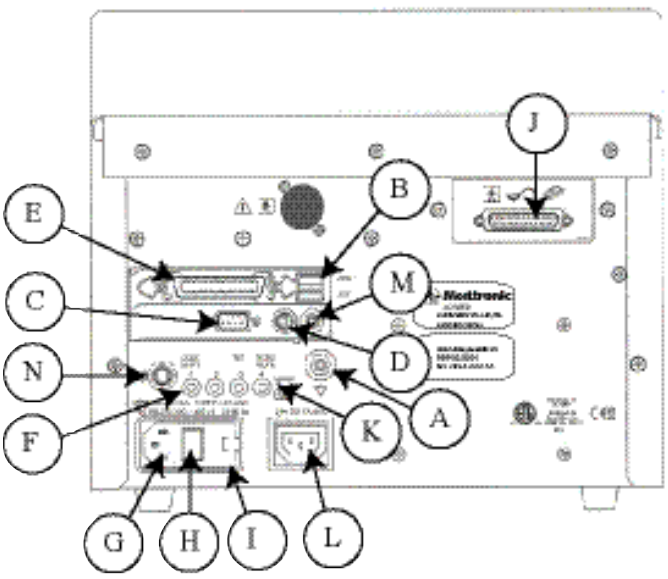

A: The **Touch Screen** displays EMG waveforms and controls many of the functions of the NIM Console.

B: The **Speaker** provides audio alarms, acoustic EMG monitoring, and voice prompts.

C: The **Software Version** installed is displayed on the start-up “splash screen”.

## 2.6 The Rear Panel

All connections to the NIM-Response® 2.0 console are via the rear panel. Please connect accessories in strict accordance with the information below.




A: **Chassis Ground**

B. **USB Out**: The USB Out is an industry standard USB type connector (two port) that can be used with mass storage devices. Note: See your sales representative for further information on the correct CF Card and reader.

C. **VGA Output**: A VGA output is available through the standard VGA 15 pin connector on the back panel. The NIM-Response® 2.0 can be connected directly to a VGA monitor.

D. **Mini Jack**: Standard configuration is for private listening through Stereo Headphones.

E. **Printer Port**: The printer port is a Centronics printer port that can be used with standard industry supported printers.

F. **Muting Probe Inputs**: There are four Muting Probe Inputs.

G. **Power Connector**: The power cord plugs into the back of the NIM-Response® 2.0 console. The input fuses and accessory output is in the power entry module. Plug the power cord into the A/C power outlet.

H. **Power Switch**: The power switch turns the power ON or OFF.

I. **Fuse Access**: The AC power fuses are located on the back of the units.

J. **Patient Interface Connector**: The patient interface connector is a 25-pin D-sub.

K. **Factory / Custom Mode Switch**: The Factory/ Custom mode switch allows the unit to be returned to original factory settings. The Custom mode ("C") allows the user to save Custom configurations.

L. **Accessory Power Outlet**: The Accessory Power Outlet powers peripheral devices used with the NIM Console.

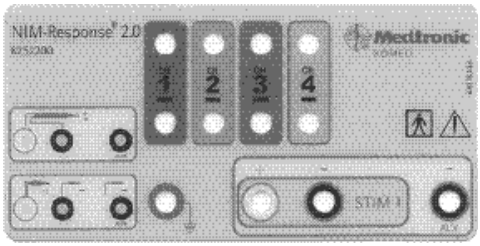
M. **RCA Audio Jack**: An RCA audio jack is provided to output an audio signal that can be overlaid onto a video signal when using industry standard recording devices. The output will be audio line level (1Vp-p).

N. For future use only.

**Important:**
Intraoperative use of the VGA Out, RCA Phone Jack, and USB Compact Flash Drive requires special considerations to remain compliant with UL2601 (IEC 60601-1). Contact Medtronic Xomed for recommendations if intraoperative use of the VGA Out, RCA Phone Jack, or USB Compact Flash Drive is

## 2.7 The Patient Interface

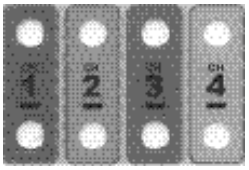
The Patient Interface and cable provide the means for connecting the patient to the NIM-Response® 2.0 console.




The NIM-Response® 2.0 patient interface has four color coded pairs of electrode inputs, a ground electrode input jack, a stimulus return input jack, plus the stimulator output that is configured to accept monopolar or bipolar stimulating probes.

**Monitoring Electrodes**

Two electrodes per channel, plus a ground electrode, are required.



(Ground connector jack)

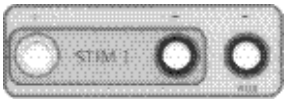
The electrode pairs for each channel plug into the color-coded paired jacks as indicated above.

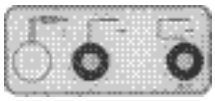
**Stimulator Connections**

The stimulator outputs can be connected appropriately for monopolar and bipolar stimulating probes, as shown below.

**Monopolar Stimulation:**

*Inputs* *Connection Diagram*





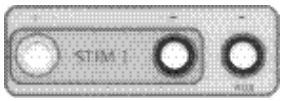
In the appropriate multi-channel electrode set, the red electrode with the white wire is used for monopolar stimulation, as the stimulus return (anode). Plug the red connector of the white electrode into the white jack with the red ring (+).

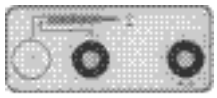
Plug the black monopolar stimulator probe connector into the black jack (-). The probe delivers current to the patient (cathode).

The auxiliary jack marked AUX (-) can be used if more than one monopolar stimulator probe is required. In such a case, both the probes share the same stimulator settings.

**Bipolar Stimulation**

*Inputs* *Connection Diagram*





When bipolar stimulation is required, only one stimulator probe can be used. The bipolar stimulator cable has a red and a black connector. Plug the red connector into the white jack with a red ring (+). Plug the black connector into the black jack (-). The black AUX (-) jack cannot be used in this application.

## 2.8 The Muting Probe

The MUTING PROBE is designed to detect the presence of noise from external devices that may cause interference on the EMG monitor. This is done by detecting current flow through the external device's cables. In the operating room environment, an electrocautery / electrosurgical unit is a typical source of this interference.

The muting probe is attached to the electrosurgical device by clamping it around the active cautery cable (not the return pad cable). In a similar manner, it may be possible to connect the Muting Probe to other equipment that may cause interference such as a CUSA, electric drills, etc. (see Section 7.2).

## 2.9 THE NIM-Response® 2.0 Patient Simulator

The NIM-Response® 2.0 Patient Simulator is intended to serve as a "patient" for the monitoring console. It may be used both for training/demonstration purposes and as a troubleshooting aid in a non-clinical setting.

For complete details of operation, please see the *Patient Simulator User's Guide* that accompanies the simulator.

## 3.0 WARNINGS AND PRECAUTIONS

It is important that the NIM-Response® 2.0 operator be familiar with this manual, its precautions, procedures and safety issues. Three labels are used in this manual to identify important concerns, conditions, or procedures:

- **Warnings:** Describes serious adverse reactions and potential safety hazards that can occur during the proper or improper use of a device.
- **Precautions:** Any special care to be exercised by a practitioner or patient for the safe and effective use of the device.
- **Additional Precautions:** Identifies conditions or practices that could result in damage to the equipment.

### Warnings

W1 The NIM-Response® 2.0 does not prevent the surgical severing of nerves. If monitoring is compromised, the surgical practitioner must rely on alternate methods, or surgical skills, experience, and anatomical knowledge to prevent damage to nerves.

W2 To avoid patient burns:

- W2a Do not activate electrosurgical Instrument while the stimulator is in contact with tissue.
- W2b Do not leave stimulating electrodes or probes in surgical field.
- W2c Do not store stimulating electrodes or probes in electrosurgical Instrument holder.
- W2d Do not allow a second surgeon (i.e. fat harvesting) to use electrosurgical instrument while stimulator is in use.
- W2e Special operator attention may be required for stimulus currents exceeding 2 mA RMS/cm2. The RMS value of current is generally lower than the stimulator current setting in mA. To calculate RMS current, waveform morphology, pulse width, repetition rate, and the stimulator current delivered must be considered.

W3 While Muting is activated, auditory and visual monitoring are disabled.

W4 To avoid false negative responses, verify stimulator current setting is high enough, and verify stimulus delivery by tone, voice, or display. Low stimulator current may cause a false negative response.

W5 High stimulator current may cause involuntary patient movement resulting in patient injury.

W6 High stimulator current activating of the fifth cranial nerve or Mastication muscles may cause tongue lacerations.

W7 False negative responses (failure to locate nerve) may result from:

- W7a Shorted EMG electrode or cabling (conductive parts of applied needle electrodes or cables contacting each other).
- W7b Patient Interface fuse blown (32 mA, 250V. Xomed Part No.: 8250615).
- W7c Patient Interface defective.
- W7d Inadequate stimulus current.
- W7e Inadequate current for stimulation of nerve through hardware, such as stimulus dissection instruments, may vary based on the physical size, shape characteristics, and design of the hardware and proximity to the nerve.
- W7f Neuromuscular fatigue from prolonged or repeated exposure to electrical stimuli.
- W7g Inadvertent simultaneous current delivery from both Stimulator (Patient Interface) probe outputs. This may result in current shunting, division between the stimulator probes.
- W7h Shorted internal amplifier (characterized by baseline activity of $< 3\ \mu V$ p-p)

W8 Do not power-on the NIM-Response® 2.0 when the stimulator is in the surgical field.

W9 To avoid eye injury during electrode placement, the electrode needles should be directed away from the globe and adequately secured with tape.

W10 To avoid the risk of fire or explosion, do not use the NIM-Response® 2.0 in the presence of flammable anesthetics and/or oxygen rich environments.

W11 To avoid electrical shock, do not attach unapproved components or accessories to the NIM.

W12 To avoid the risk of infection while using the NIM-Response® 2.0 touchscreen stylus, the user must maintain good sterility practices.

W13 Electrocardiogram monitoring artifacts may be caused by NIM-Response® 2.0 stimulus current delivery or EMG electrode impedance monitoring.

W14 Direct stimulator contact may disrupt the operation of active implanted devices.

W15 While stimulating, it is recommended to use only approved EMG monitor(s) equipped with active audio and/or visual current delivered feedback systems to ensure delivery of current to intended tissues.

W16 Proper handling, insertion, and placement of electrodes and probes is critical for safe and accurate EMG monitoring:

W16a Improperly placed or bent needles increase the risk of needle breaking off in the patient.

W16b Do not attempt to straighten bent needles because this may cause stress and weaken device, causing needle to break off in patient.

W16c Extreme care must be taken when handling instruments with sharp points or edges.

W17 The surgical practitioner must choose the appropriate size electrodes and probes based on the procedure to be performed and the stimulating current necessary for the application.

W18 Avoid trans-thoracic stimulation; when possible, maintain anode and cathode stimulating sites in close proximity.

W19 Reuse of single use electrodes and probes increase the risk of infection and may cause degraded or ineffective monitoring.

## Precautions

P1 Special care must be exercised to distinguish between the high-pitched beep of the Event Tones (EMG activity over threshold), and the Stimulus Warble Tone (indicates the set current is being delivered).

P2 When the "Bleedle Alarm" (BLEE-dle-DEET) sounds, the cause must be identified and eliminated immediately.

P3 To avoid loud, extraneous monitoring noise during electrosurgical unit activation, ensure the Muting Probe is properly attached to the active electrosurgical lead.

P4 Inadequate stimulus current flow may be caused by non-flush contact between the stimulating electrode or probe and the nerve, inadequate stimulator probe electrical contact surface area, or high impedance.

P5 Inability to deliver stimulus current flow may be caused by:

P5a Stimulator return electrode not connected, or other incomplete electrical connection between the NIM-Response® 2.0, monitoring electrode and stimulator probe.

P5b STIM 1 (EMG) Patient Interface fuse blown (32 mA, 250 V, REF 8250615).

P5c Stimulus set to 0.00 mA.

P5d Defective stimulating electrode or probe.

P6 To avoid false positive EMG events (stimulus artifacts):

P6a Ensure the recording electrodes and the stimulator (+) or (-) cabling are routed separately and not tangled.

P6b Ensure EMG ground (green wire) is physically placed between the stimulator return electrode (white wire with red plug) and the EMG channel input electrodes.

P7 Proper placement and setup of the electrosurgical unit away from the NIM-Response® 2.0 will reduce or minimize unnecessary muting, interference, and offsets.

P8 Use of unapproved stimulators, stimulus probes, stimulus-dissection instruments or electrodes may result in compromised NIM-Response® 2.0 operation, such as, but not limited to, decreased accuracy.

P9 Electrode integrity should be checked (on the "electrodes" screen) after electrode insertion and before electrode removal to give additional assurance that electrode continuity was maintained throughout the entire procedure. If electrode impedance is very high, discontinue use and replace.

P10 The Patient Interface cable, and Muting Probe cable should be secured to the floor with tape or other non-trip device.

P11 Excessive or insufficient muting may result from improper muting gain. For excessive muting, move the Muting Probe to a lower jack number. For insufficient muting, move the Muting Probe to a higher jack number. Standard position is number 3.

P12 To avoid excessive muting:

P12a Do not place the NIM-Response® 2.0 in close proximity to the electrosurgical unit.

P12b Do not place Patient Interface or electrode wires in close proximity to the electrosurgical unit or electrosurgical unit wires.

P12c Avoid high-power electrosurgical unit monopolar settings. Note that muting caused by electrode charging may last several seconds after electrosurgical Instrument use.

P12d Be aware of external sources that may induce muting including cellular phones, diathermy, electrocautery used in adjacent operating rooms, or other sources of electromagnetic interference.

P13 Avoid accidental contact between connected but unapplied electrodes and other conductive parts.

P14 Contaminated single use electrodes and probes must be disposed of in an appropriate sharps biohazard container in accordance with hospital or other user facilities policy.

P15 For extra-ocular monitoring, it is recommended that electrode placement be done under the direction of a neurologist or ophthalmologist.

P16 The Patient Interface safety fuse used in all NIM Patient Interfaces Boxes for the Stimulator Output are specifically tested for ECU protection.
Use Xomed 11270048 Fuse, 5 x20mm, 32mA, 250 V. Order 8250615 Fuse Kit for replacements.

## Additional Precautions

AP1 To avoid system damage, do not connect any device **other than** NIM-Response® 2.0 Muting Probes into any of the four muting probe inputs on the rear panel of the NIM-Response® 2.0.

AP2 Disconnect the power of the NIM-Response® 2.0 or a connected printer before cleaning. To prevent cleaning solutions from seeping into the electronic portions of the instrument, spray cleaner lightly on a cotton cloth, then wipe the instrument with the cloth. Be especially careful around the controls, connectors and panel edges. Do not use abrasive cleaners (especially on the touch screen).

AP3 Repair and/or modification to the NIM-Response® 2.0, or any accessory by anyone other than qualified service personnel may significantly compromise the units ability to monitor nerve activity and/or void the equipment warranty. For best performance, it is recommended that all service be performed by Medtronic Xomed service personnel. **The Manufacturing Test is not intended for end users and is to be used only under the direct supervision of Medtronic Xomed Personnel (see section 7.13).**

AP4 Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this Guide.

AP5 Portable and mobile RF communications equipment can affect Medical Electrical Equipment.

AP6 Use of accessories and cables other than those specified and sold by Medtronic Xomed may result in increased emissions and decreased immunity of this unit.

AP7 The NIM-Response® 2.0 should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the NIM-Response® 2.0 should be observed to verify normal operation in the configuration in which it will be used.

## 4.0 POWERING UP THE NIM-Response® 2.0

**4.1 Self test** An internal integrity check is automatically performed each time the system is turned ON**. (See Warning W8)** On Power-up a series of messages are briefly displayed including the software version number and revision date, then the console does a series of self-tests on the hardware:

**MASTER PROGRAM -** Master program files are checked for integrity.
**MASTER RAM -** Checked to ensure enough extended memory exists.
**TOUCH PROGRAM -** The touch screen controller is checked for the correct revision number.
**TOUCH RAM -** The touch screen controllers RAM is checked by writing to each location.
**WATCHDOG TIMER -** The touch screen controllers communication link is tested.
**A TO D SPEED -** The display shows the Analog to digital speed test results.
**SYSTEM MEMORY -** The memory is checked for the existence of the configuration files.
**LANGUAGE** – The display shows the selected language.
**CONFIGURATION –** The display shows the current configuration (factory or custom).

### 4.2 Touch Screen Calibration

If the touch screen responds in an unexpected manner or registers a press in the wrong area of the screen, it may need calibrating.

**Note:**
For the highest accuracy, it is recommended that you calibrate the screen using a stylus rather than a fingertip.

**Calibrate the screen as follows:**

1. Turn the power OFF for at least 5 seconds, and then turn it ON again.
2. When the "Splash Screen" (with the device name and Medtronic logo) appears, press the screen until you are prompted to remove your hand by the text message *"Please remove your hand from the screen to continue"*.
3. The screen will then display two buttons, the large one at the top is labeled: *"Touch Screen Calibration"*. Press this button.
4. The screen will then display the text message: *"Touch the lower left of the screen"* - precisely press the lower left corner of the display screen.
5. The screen will then display the text message: *"Touch the upper right of the screen"* - precisely press the upper right corner of the display screen.
6. The screen will then display the text message: *"Press circle to verify calibration"* - precisely press the center of the circle displayed on the screen.
7. If the touch screen does not "sense" the final touch as being in the center of the displayed circle, the calibration sequence will repeat. On successful completion of the calibration, the NIM will enter normal operating mode.

## 5.0 Audio – Understanding What You Hear

The NIM-Response® 2.0 Nerve Monitor produces many different sounds throughout surgical procedure that require understanding by the person performing monitoring. In addition to EMG sounds, various beeps and voices provide useful information.

### 5.1 Alarms

The alarms draw attention to any condition, which prevents proper monitoring. None of the audible alarms should be ignored. One must assume that valid monitoring has stopped and determine immediately why the alarm sounded. There are three distinct alarms:

5.1.1 **BEEP Alarm**

The high-pitched, repetitive beep is used to register failure of internal microprocessor hardware. If you hear it at any time other than at power up, stop using the NIM-Response® 2.0 System and contact MEDTRONIC XOMED Customer Service (see Section 2).

5.1.2 **BLEEDLE Alarm**

This is a three-note alarm (BLEE-dle DEET) that cannot be disabled. It repeats until the responsible condition is remedied. The alarm is heard under the following conditions:

- Check Electrode - Contact with an electrode is lost. On the main menu the channel in question will be flashing. After 20 seconds, the electrode Impedance screen will turn on. The bleedle alarm will repeat every 20 Seconds until the condition is remedied. This is followed once by the "CHECK ELECTRODE" voice unless this has been disabled.

- Muting - The NIM-Response® 2.0 System has been in MUTE mode for more than 30 seconds (unless you are in ELECTRODE CHECK). The bleedle alarm is followed once by the "MUTING" voice and will repeat every 30 seconds until the condition is remedied.

**Precautions**

P1 Special care must be exercised to distinguish between the Event Tones (EMG activity over threshold), and the Stimulus Tone (indicates the set current is being delivered).

P2 When the "Bleedle Alarm" (BLEE-dle-DEET) sounds, the cause must be identified and eliminated immediately.

5.1.3 **Voice Alarms**

There are two voice alarms that are selectable, and work in unison with the bleedle alarm. They can be turned on or off and have volume controls. These alarms are "check electrodes" and "muting," and are described in 5.1.2.

5.1.4 **Voice Annunciation**

There are several voice annunciation types, stimulation delivery confirmation, numeric stimulator current values, and activation of auto threshold.

NIM-Response® 2.0 Voices:

| | | |
|---|---|---|
| Point | Five | Baseline increased |
| Zero | Six | Check electrodes |
| One | Seven | Electrodes |
| Two | Eight | Muting |
| Three | Nine | Stimulus |
| Four | Baseline decreased | |

## 5.2 EMG Audio

The EMG audio is the amplified sound of muscle activity that is heard instantaneously as the nerve is stimulated. All EMG activity, regardless of amplitude, is audible when the EMG audio is ON. The EMG activity may sound like a low-pitched "drumbeat", a high-pitched "crackle," or a "growl". When multiple channels are monitored, it is unlikely that you will be able to differentiate the EMG signals as to their channel of origin strictly by the sounds they produce.

5.2.1 **Event Tones**

Event Tones are heard when the EMG amplitude is larger than the Event Threshold setting. The Event Tones are easily heard over O. R. noise and are heard at the same time with the EMG audio, previously mentioned. The Event Tones are different for each channel so that the channel of origin can be distinguished. The tone for channel 1 activity is lower in pitch than the channel 2 tone and so on for channels 3 and 4. This lets you tell by the tone's pitch which channel is involved. When EMG activity exceeding the event threshold occurs at the same time on multiple channels, only two of the tones sound at once.

5.2.2 **Baseline – Voice**

The NIM-Response® 2.0 has two (2) baseline voices: "BASELINE INCREASED" - "BASELINE DECREASED".

These voices are used as part of the Auto Event Threshold feature when automatic adjustments are made. Please see the Auto Event Threshold section of the manual.

5.2.3 **Stimulus**

5.2.3.1 **Stimulus - Tone**

The stimulus tone announces the delivery of current to the patient.

- If STIMULUS, CONTINUOUS is used, then delivery of stimulus current is accompanied by a continuous, warbled, high-low tone (referred to as "Stimulus Warble Tone").
- If STIMULUS, BRIEF is used, then delivery of stimulus current is accompanied by a brief warbled tone.

**Note:** Stimulus tones will not sound for stimulus current levels below 0.05 mA. Stimulus tones are not heard if an Event Tone has been generated.

5.2.3.2 **Stimulus - Voice**

The stimulus voice announces the delivery of current to the surgical field by voice.

- "STIMULUS" VOICE
  With "Stimulus", delivery of current to the surgical field is announced by the word, "STIMULUS". It may be turned on or off and has volume control.
- "SETTING" VOICE
  The "Setting" voice announces the value of the STIMULUS setting. It also announces any new stimulus setting when adjustments are made. Example: 0.50 mA would be announced as "Point Five". It may be turned on or off and has volume control.

**Note:** Setting voice or "Stimulus" voice will not sound for stimulus current levels below 0.05 mA. Stimulus voices are not heard if an Event Tone has been generated.

5.2.4 **Other EMG Responses**

5.2.4.1 **BURST** - Brief tone
Caused by electrical stimulation, direct nerve contact, irrigation, or thermal changes.

5.2.4.2 **TRAIN** Tones lasting seconds to minutes
Caused by nerve excited/irritated, irrigation, drying, bumping, or anesthesia.

5.2.4.3 **PULSE** - Repeated tones

**Warnings**
W3 While Muting is activated, auditory and visual monitoring are disabled.

# 6.0 SCREEN AND CONTROL DESCRIPTIONS

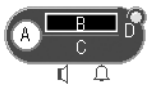
## 6.1 General User Interface Overview

The touch-sensitive areas of the screen provide information and control options. Some of these options are:

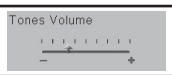
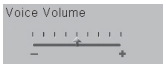
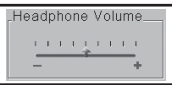
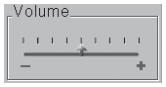
### 6.1.1 Preference / Control Options

| Illustration | Name | Action |
|---|---|---|
| ○ ● | On/Off Indicator | |
| ◉ ○ | Radio Buttons | For preference selection where selecting one Radio Button will automatically deselect another. |
| ☑ ☐ | Check Boxes | For preference selection. |
| ▲ ▼ | Scroll Buttons | For viewing a list. |
| ▲ ▼ | Coarse Adjust Buttons | For rough or fast adjustment. |
| ▲ ▼ | Fine Adjust Buttons | For fine-tuning of an adjustment. |

### 6.1.2 Channel Button

| Illustration | | Name | Action |
|---|---|---|---|
|   | | Channel Button | Toggle Button - turns channel On/Off. If "Channel Mute" is selected (Settings/Audio) button rotates through a series of On/Off functions. |
| | A | Channel Number | Displays Channel Number. |
| | B | Micro Volt Activity | Displays Baseline Activity or Event peak value. White box indicates channel with highest level of activity. |
| | C | Muscle Group Name | Displays name of Muscle Group assigned to |
| ○ ● | D | On/Off Indicator | Indicates On/Off status of channel. |
| If "Channel Mute" is selected at Settings/Audio | 🔔 | Bell Icon | Indicates that Event Tones are turned on, and can be turned Off/On using the Channel Button. |
| | 🔈 | Speaker Icon | Indicates that EMG Audio is turned on, and can be turned Off/On using the Channel Button. |

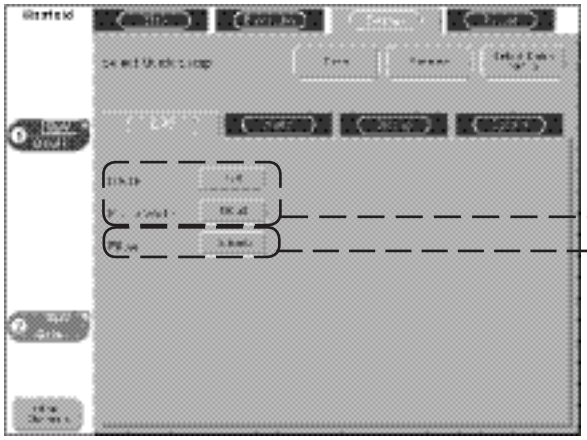
### 6.1.3 Volume

| Illustration | Name | Action |
|---|---|---|
|   | Settings/Audio Tones Volume | Tones volume adjustment secondary to Main Screen Volume. |
|   | Settings/Audio Voice Volume | Voice volume adjustment secondary to Main Screen Volume. |
|   | Settings/Audio Headphone Volume | Headphone volume adjustment secondary to Main Screen Volume. |
|   | Main Screen Volume | Main or primary volume adjustment. All other volume slide bars are subordinate. Example increasing main volume 10% increases all volumes 10%. |

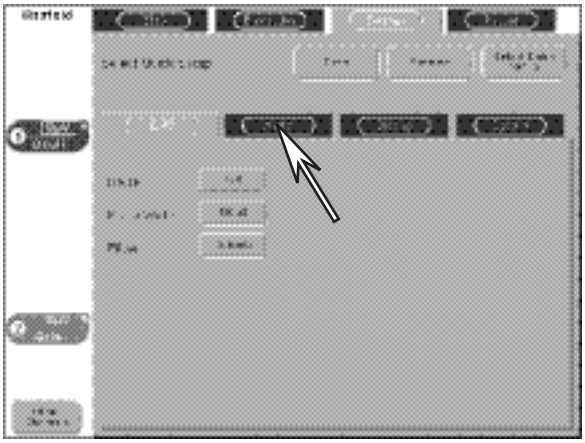
## 6.2 Settings: EMG Tab

Press the “EMG”, “Electrodes”, “Settings” and “Patient” tabs to toggle between the primary screens. For saving settings, please see Section 9.3.

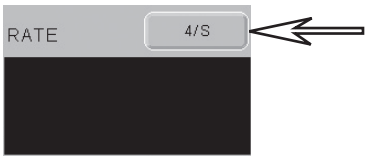
**SETTING: EMG**



- Setting stimulating options
- Setting Filter

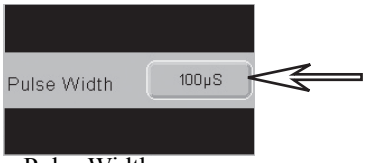


1. Change to Audio Screen.



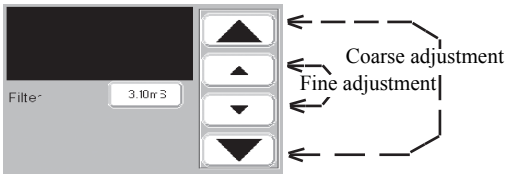

Adjusting Rate

1. The button display will toggle through the pre set values with each press.

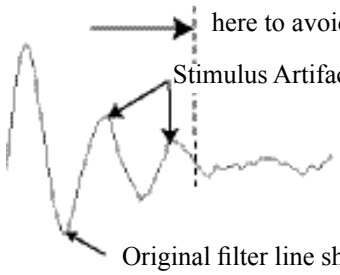



Adjusting Pulse Width

1. The button display will toggle through the pre set values with each press.

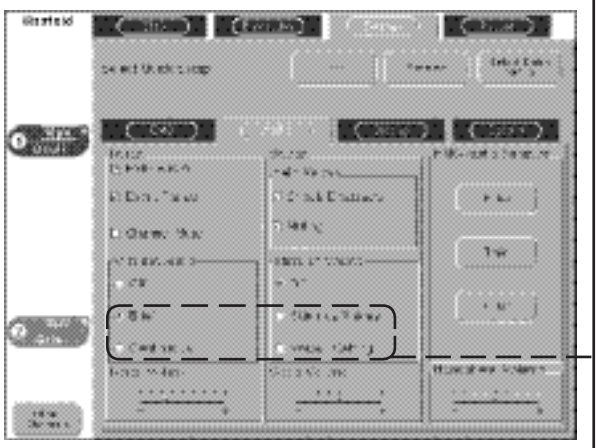



FILTER - An adjustable delay allowing the small amount of electronic noise caused by stimulation (Stimulus Artifact) to stabilize before reading EMG data.



## 6.3 Settings: Audio Tab – Selecting audio options

**SETTINGS: AUDIO**

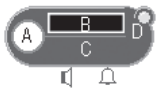


1. Select desired options.
2. Change to Settings: Display.

**NOTE:**
Of the four radio buttons, Brief, Continuous, Voice Setting, and Stimulus Voices one is always selected while the other three are automatically deselected.

**Tones**
**EMG Audio:** Applies Raw EMG to the speakers.
**Event Tones:** Any event is heard as a beep.
**Channel Mute:** Enables the "Tones" and "Audio" icons on the "Monitoring Screen".

EXAMPLE



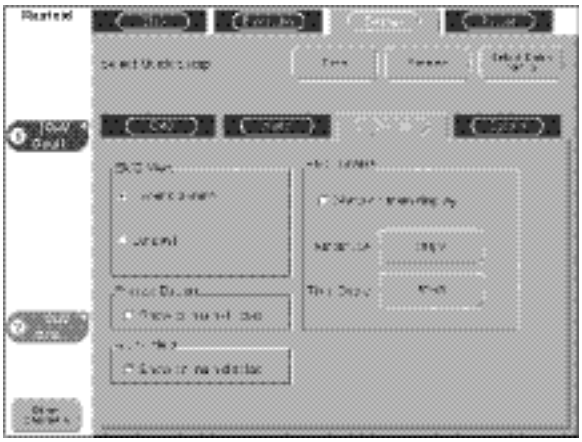

**Stimulus Audio**
**Brief:** Stimulation is a "BLEE-dle DEET Tone".
**Continuous:** Stimulation is a "Warble Tone".

**Help Voices**
**Check Electrode:** Sounds when contact with an electrode is lost.
**Muting:** Sounds when system has been in MUTE for more than 30 seconds.

**Stimulus Voices**
**Stimulus Voices:** Stimulation is announced by "STIMULUS".
**Voice Setting:** Stimulation is announced by the setting.
Example: 0.50 mA would be announced as "POINT FIVE".
Also announces new settings when stimulus is changed.

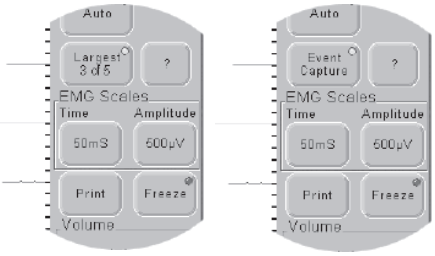
## 6.4 Settings: Display Tab – Display Adjustments

**SETTINGS: DISPLAY**



1. Select options and/or adjust Amplitude and Time.
2. Change to Settings: System.

Example of Main Display
Showing Quick Help, Freeze, Time, Amplitude and Largest (left), Event Capture (right), buttons on the main display.



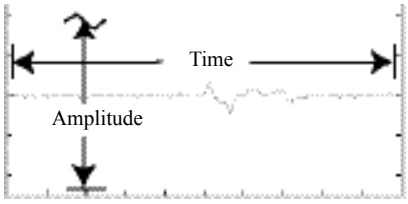

**EMG View**
Select **"Event Capture"** or **"Largest"** for display on the main screen.

**"Show on Main Display"** enables display buttons for:
Freeze, Quick Help, EMG Scales (Time and Amplitude) on the main display.

**EMG Scales, Amplitude and Time**
Controls how an EVENT is displayed.

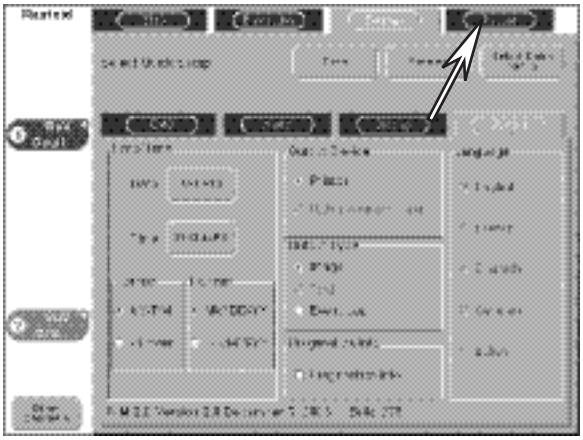
- **Amplitude** - Vertical portion of the EMG display.
- **Time** - Horizontal portion of the EMG display.

Note: Changing the scales only affects how the data appears on the screen. It does not modify the sensitivity of the unit.



## 6.5 Settings: System Tab

**SETTINGS: SYSTEM**



1. Select options.
2. Change to Patient Screen.

**Date/Time**
Format: AM/PM or 24 hour clock and month-day-year or day-month-year arrangement.
Date/Time Buttons: Opens Keypad for entering Date/ Time.

**Output Device**
Used to select WHERE data is sent (Printer or Compact Flash.

**Output Type**
Used to select the format of the data output.

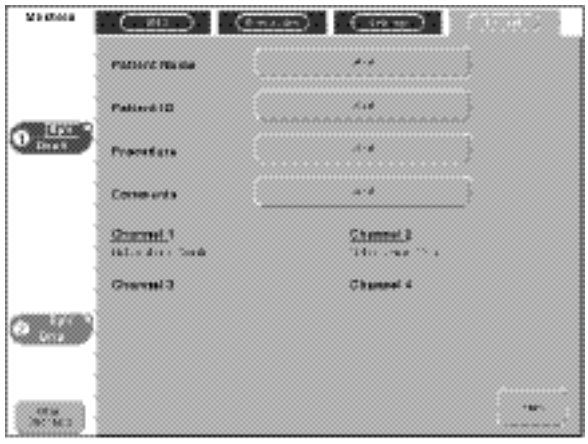
| | |
|---|---|
| Image | Screen image is sent to the printer or Compact Flash. |
| Text | Comma-delimited EMG waveform data is sent to the printer. |
| Event Log | The last 300 detected events are sent to the printer or Compact Flash in a log output format. |

**Diagnostics Info** – is for use under the supervision of qualified service personnel ONLY.

**Language**
Used to select current display language.

## 6.6 Patient Information

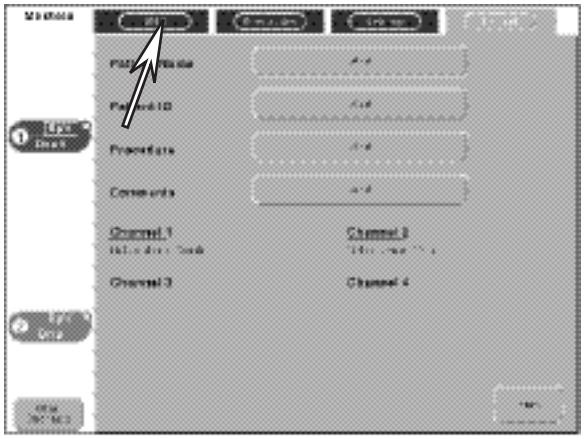
**PATIENT INFORMATION**



- Add Patient, Patient ID, Procedure and Comments to Saved or Printed Events.

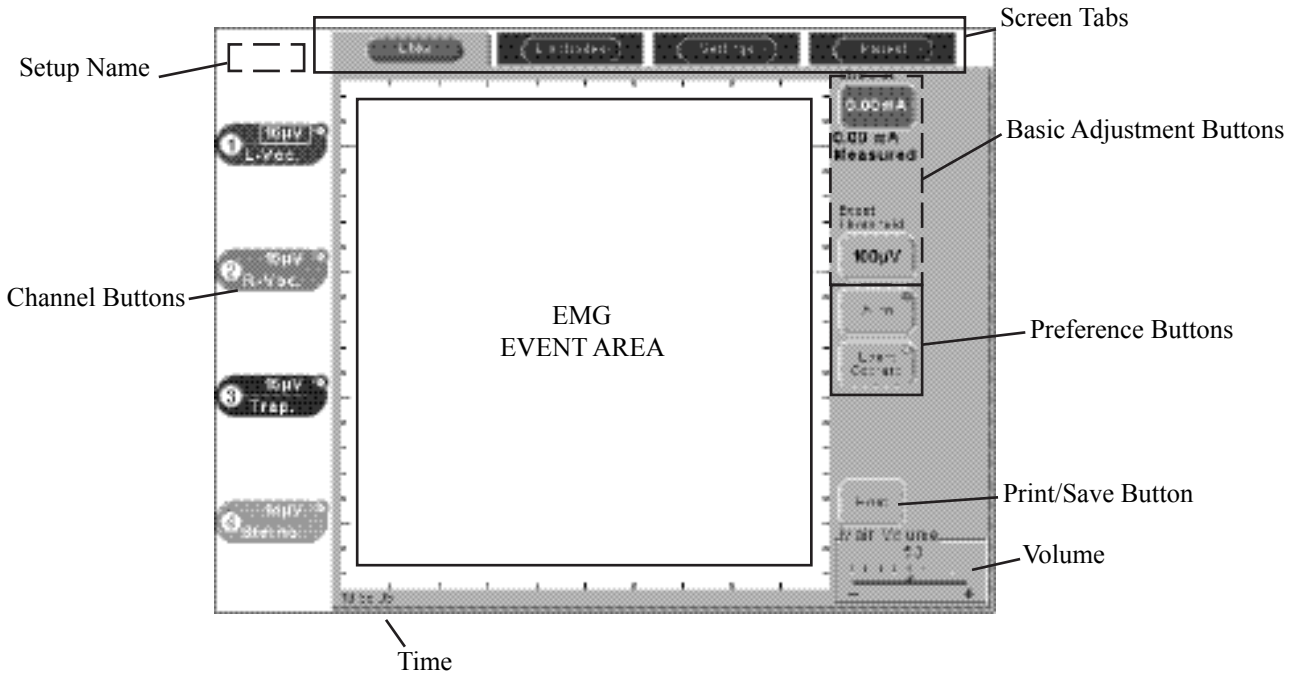
**Patient buttons**

- Each button opens a keyboard for data entry.



1. Change to Main Display (EMG Tab).

## 6.7 The Main Display




## 6.8 Reading the EMG Screen

The amplitude of the signal is represented by the vertical portion of the EMG display. The amplitude scale is user-adjustable (see Section 6.11). The screen is divided into 40 divisions with each channel centered at 5 divisions (2 and 1/2 positive, 2 and 1/2 negative).

**Note:** Changing the scale only affects how the data appears on the screen. It does not modify the sensitivity of the unit.

The horizontal portion of the EMG display represents time and the scale is also adjustable (see Sec 6.11). The screen is divided into 10 divisions. This differs from the "Amplitude scale" in that the "Time scale" selection is the entire horizontal portion of the screen.

**Note:** Changing the scale only affects how the data appears on the screen. It does not modify the sensitivity of the unit.

## 6.9 Stimulator adjustments

Adjusting the Stimulator. Stimulator adjustment involves the current adjustment shown here as well as the Rate, Pulse Width, and Filter adjustments shown in section 6.2.

**Important Note:**

The absolute stimulus intensity required to adequately stimulate any motor nerve is determined by a complex combination of several factors including (but not limited to) the following:

- The functional health of the nerve itself.
- The type of stimulation probe used (monopolar or bipolar).
- Proximity to the nerve.
- The pulse width of the stimulus.

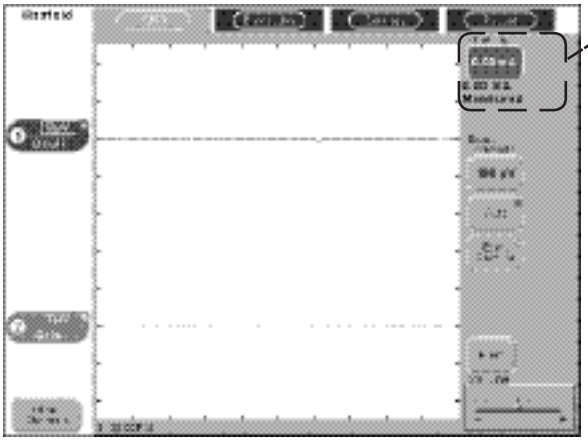
You should use the smallest amount of stimulus necessary to elicit a detectable EMG event. Stimulus current levels of 0.3 mA may be high enough for adequate direct monopolar stimulation of the facial nerves, but may elicit little or no response when monitoring motor evoked potentials. The best guideline for setting the stimulus intensity level is to use the lowest amount of stimulation that produces an EMG event.

**The surgeon should be aware:**

- That STIMULUS is **continuously** being applied to the STIMULATOR probe.
- STIMULATING the patient is the result of physical contact between the patient and the STIMULATOR probe.
- The STIMULATOR probe should be kept ISOLATED when NOT STIMULATING the patient.

**Stimulator adjustments continued**

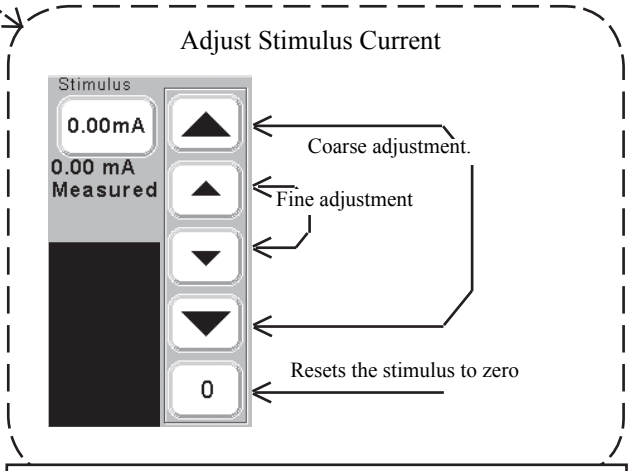
**MAIN DISPLAY (EMG SCREEN)**



Notice additional display features:

- Time, Amplitude, Freeze, and Quick Help (? Button) are turned on at Settings: Display Screen.

1. Press mA button to open adjustment arrows.

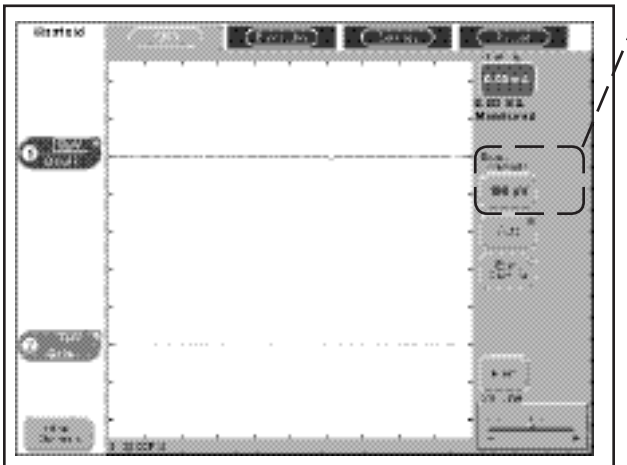



**Note:** To prevent inadvertent high stimulus levels, the first time in a procedure when a stimulus level exceeds 3 mA, a dialog box will open:

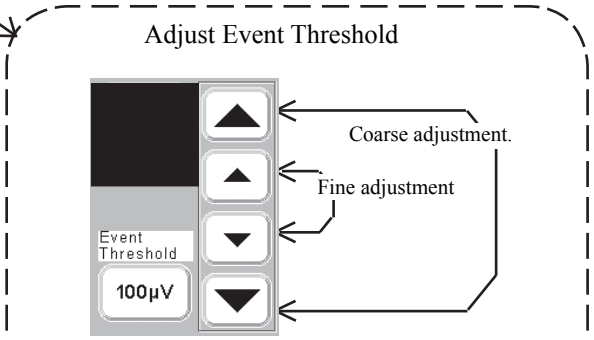
**STIM 1 LEVEL WARNING**
Stim 1 in excess of 3 mA
Press OK to allow stimulus

## 6.10 Adjusting the Event Threshold

See Section 7.3 for details.



- EVENT THRESHOLD is a highly sensitive filter used to define where EMG activity becomes significant.
- EMG activity exceeding this “THRESHOLD” is defined as an “EVENT” and results in Event Tones (alarms) sounding.



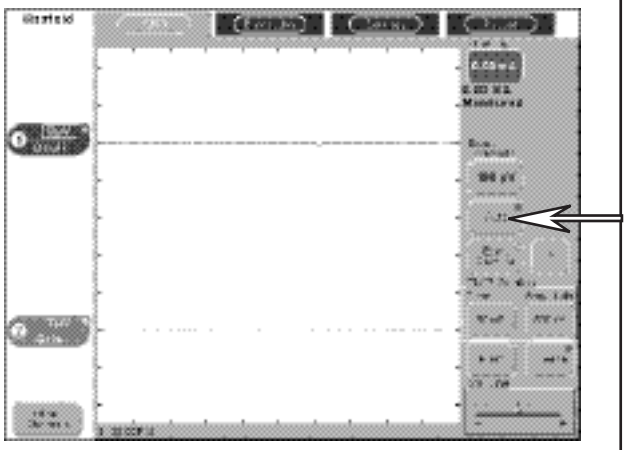

Coarse adjustment is in increments of 50.0 µV.

Fine adjustment is in increments of 5.0 µV.

Note: Total adjustable range is 20 µV to 2500 µV.

## 6.11 Other EMG screen adjustments / selections

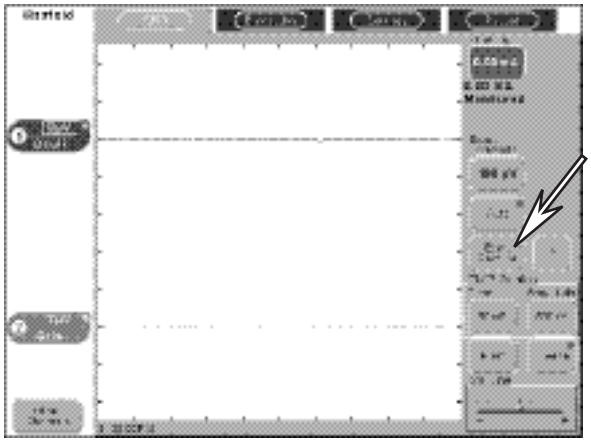
**Auto Event Threshold** (see Sec. 7.3)



Auto Threshold is used in a situation where the nerve is irritated causing elevated EMG baseline, the NIM will sound constant Event Tones (excessive noise) and will stop becoming useful.

(ON/OFF button) can automatically adjust the Event Threshold to maximize information and minimize unnecessary noise.

**Event Capture or Largest** (see Sec. 7.3)



This button shows either **Event Capture** or **Largest** depending on the selection made in the Settings screen.

Event Capture

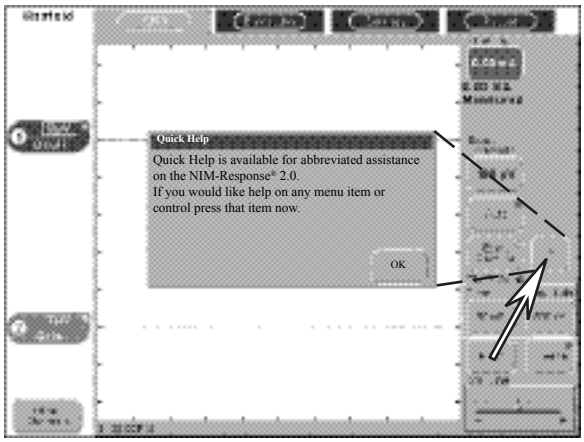
Captures and holds EMG activity that exceeds the EVENT THRESHOLD.

Largest

Displays on the screen the largest event from a series of events.

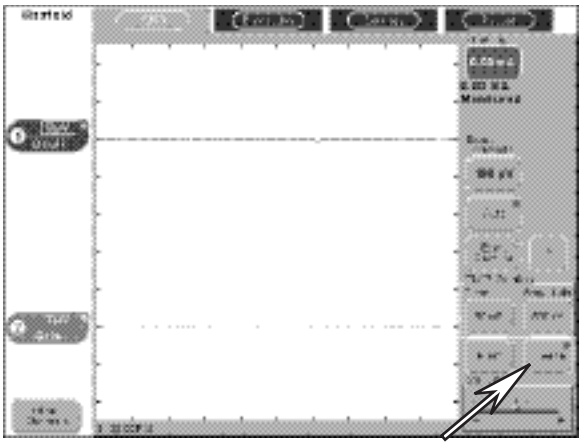
Events occurring at intervals greater than 4 seconds will be displayed as 1 of 1.

**Quick Help** (see Sec 7.5)


Quick Help
Quick Help is available for abbreviated assistance on the NIM-Response® 2.0.
If you would like help on any menu item or control press that item now.
OK

Quick Help is available as abbreviated assistance on the Main Display providing it is turned on at the Settings/Display screen.

**Freeze** (see Sec. 7.4)

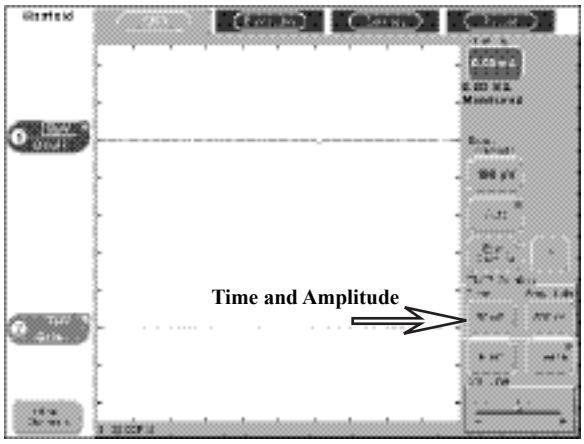


**Freeze**, will hold the current screen and the button will flash from gray to white.

Press again to unfreeze the screen.

**Note**: Any events that take place when Freeze is ON are LOST.

**Time and Amplitude** (see Sec 6.4)




EMG Scales, Amplitude and Time Controls how an EVENT is displayed.

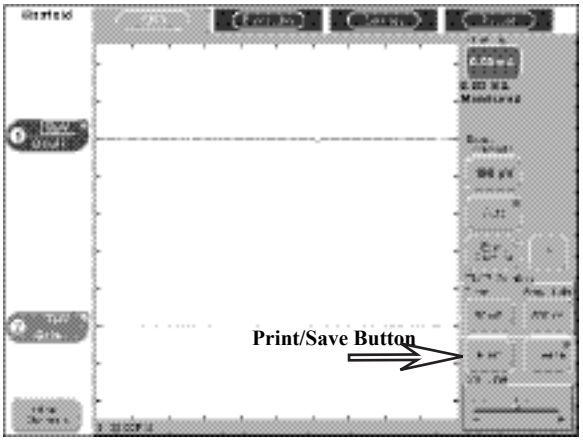
Adjusting Amplitude - Vertical display.

1. The button display will toggle through the pre set values with each press.

Adjusting Time - Horizontal display.

1. The button display will toggle through the pre set values with each press.

**Sending Data to the selected Output Device** (see Sec 7.8)



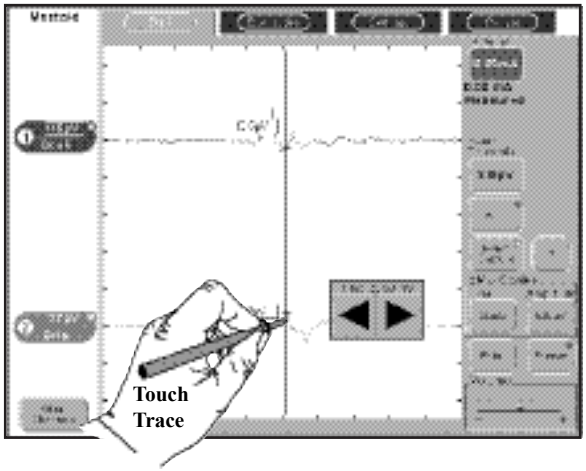

Print or Save must be selected on Setting/System

Print sends the current display, as an image or text, or the event log, as text, to the Printer.

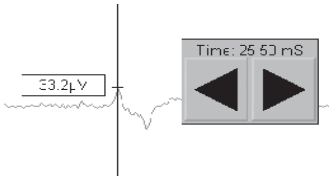
Save sends the current display, as an image or text, or the event log, as text, to the USB compact flash disk.

Note: See your sales representative for further information on the correct CF Card and reader.

**Measurement Cursor** (see Sec 7.7)




To view details of the event waveform, touch the trace at the point of interest.




The amplitude will be displayed at the selected point. The time from zero (known as latency) will be displayed above the left/right increment buttons.

Time buttons will move the vertical line left or right in increments of 0.25 ms. Voltage is read from 0 at Baseline to the value at the intersection of the vertical line. Negative numbers (numbers below Baseline) appear with a minus sign in front of the value, where positive numbers have no character in front.

The cursors and displayed measurements will automatically turn off after 30 seconds of inactivity, or when another location is touched.

# 7.0 SPECIAL FUNCTIONS AND FEATURES

## 7.1 Channels

Up to four channels can be monitored simultaneously. During power-up, the NIM-Response® 2.0 automatically turns on each channel that has a patient connected electrode present (if no electrodes are connected, channels 1 and 2 are turned on automatically).
When event capture is OFF, the channels "Baseline Activity" is displayed on the top half of the channel label. If event capture is ON, the displayed value will reflect the amplitude of the last "Event" on the monitored channel(s).

## 7.2 Muting

The Muting Probe is normally clamped around the active cable of an electrosurgical instrument that would otherwise be interfering with monitoring. Do not include the grounding pad cable in the jaws of the muting probe. It may also be connected to other electrical cables of equipment, such as bipolar electrocautery, ultrasonic debulking devices (e.g. CUSA), or other external devices, which generate interfering signals. Always attach the Muting Probe close to the output jacks of the electrosurgical or other unit rather than near the hand piece the surgeon uses. More than one output cable may be clamped within the Muting Probe jaws at one time.

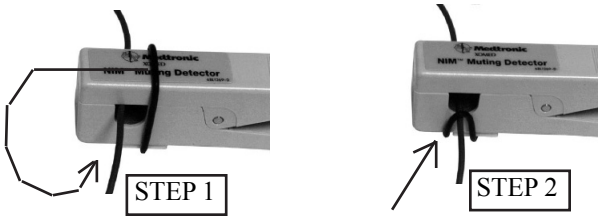



**FIGURE 1**
Monopolar Electrosurgical Instrument Clamping

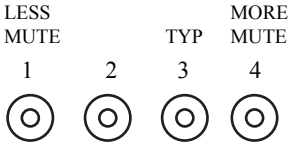
**FIGURE 2**
Monopolar and Bipolar Electrosurgical Instrument Clamping

### 7.2.1 Muting Probe Set up

1. Open the Muting Probe jaws and insert the cable from the electrosurgical instruments, ensuring that the wire is free to move and the jaws are completely closed.
2. For monopolar cables, route the wire straight through the clamp.
3. For bipolar cables, route a single conductor of the bipolar cable straight through the clamp. For very low power levels it may be necessary to loop the single conductor around and through the clamp once.
4. Slide the cable so the probe is near the main unit of the electrosurgical instruments, not near the hand piece(s).
5. Slip the upper side of the anti-slide ring around the end of the Muting Probe to form a "U" around the cable. Pull it snugly against the probe's lower jaws (see Fig 1, Steps 1 & 2).
6. Do not clip the muting probe to the grounding pad cable.
7. The Muting Probe and Patient Interface cables should be secured to the floor with tape or other non-slip/trip device.

### 7.2.2 Muting Probe Inputs

Insert the MUTING PROBE into one of the MUTING PROBE INPUT jacks on the rear panel of the NIM-Response® 2.0.




There are four input jacks for MUTING PROBE input. These four input jacks are individually preset to represent a graduated muting gain. Input jack #1 is the least sensitive for muting detection, while input jack #4 is the most sensitive. Jack #3 provides the "typical" gain value for the muting detection feature. (See table next page).
The following table shows the minimum power level for satisfactory muting performance under various combinations of electrosurgical unit type (monopolar or bipolar), and muting probe jack position:

| Muting Probe Jack position | Monopolar Electrosurgical Unit | Bipolar Electrosurgical Unit | Bipolar Electrosurgical Unit |
|---|---|---|---|
| | | Wire straight through clamp (no loop) if power is: | Wire looped through the clamp if power is: |
| 1 | 22 W | > 50 W | < 50 W |
| 2 | 10 W | | |
| 3 | 6 W | > 14 W | < 9 W |
| 4 | 2 W | > 14 W | < 2-3 W |

Should there be a need for more or less gain, depending upon the conditions of the operating room setting or amount of detection desired from a given electrosurgical unit, simply move the muting probe into a more appropriate jack.

**Warning**

W3 While Muting is activated, auditory and visual monitoring are disabled.

**Precaution**

P11 Excessive or insufficient muting may result from improper muting gain. For excessive muting, move the Muting Probe to a lower jack number. For insufficient muting, move the muting probe to higher jack number. Standard position is number 3.

P12 To avoid excessive muting:
Do not place the NIM-Response® 2.0 in close proximity to the electrosurgical unit.
Do not place Patient Interface or electrode wires in close proximity to the electrosurgical unit or electrosurgical unit wires.
Avoid high-power electrosurgical unit monopolar settings. Note that muting caused by electrode charging may last several seconds after electrosurgical instrument use.
Be aware of external sources that may induce muting including cellular phones, diathermy, electrocautery used in adjacent operating rooms, or other sources of electromagnetic interference.

**Additional Precaution**

AP1 To avoid system damage, do not connect any device other than NIM-Response® 2.0 Muting Probes into any of the four muting probe inputs on the rear panel of the NIM-Response® 2.0.

#### 7.2.3 Susceptibility to Radiated Electromagnetic Fields (RFI)

Complies with EN 60601-1-2; 2004.
The system is intended to be used with the Muting Probe which generally activates the MUTE function synchronous with exposure to excessive RFI energy. During Muting the audio and visual displays are disabled. After removal of the RFI, the muting turns off and monitoring automatically continues. Certain sources and low levels may not be detected by the muting detector and may not activate the mute function.
Users of this equipment should be aware that if the Muting Probe is not used or is not activated by the RFI, then the monitor as a result of the interference may output audio and visual interference artifacts. When the unit was RFI tested without the Muting Probe, artifact was heard from the speaker and seen on the display for RFI levels from 1 V/m (80% AM 1 KHz) to 3 V/m for 26 to 1000 MHZ.
Artifact will typically produce screen and/or speaker output that has characteristics unlike repeatable evoked EMG responses. The user should confirm that the responses are not RFI induced and that EMG clearly correlates with an expected patient EMG response in the context of the surgery.
RFI artifact responses cannot convey improper information since the aberrant signal is easily recognizable by the surgical team.

## 7.3 Event Threshold, Auto, Event Capture and Largest

#### 7.3.1 Event Threshold

The Event Threshold is the parameter that defines where EMG activity becomes significant. EMG activity exceeding this user-set “Threshold” is defined as an “Event” and results in the sounding of the Event Tones (alarm).
The Event Threshold is set on the EMG screen, as described in Section 6.10.

#### 7.3.2 Auto

In a situation where the EMG activity has exceeded the Event Threshold for 10 – 20 seconds the Event Tones are continuous & thus are less useful (if it is considered that this alarm response is not significant). At such times, it may be useful to adjust the Event Threshold to a new, higher value.
Setting the Auto Event Threshold “On” (see Section 6) will enable an automatic increase in the Event Threshold to the calculated mean level over the past 10 – 20 seconds.
All activity less than the new Event Threshold will be heard as raw EMG, whereas EMG activity greater than the new Event Threshold will generate Event Tones. Additionally, if the Voice setting is selected, it will announce the amount of baseline increase. The Event Threshold will return to the original value after 10 – 20 seconds of no, or decreased, event tone activity.

7.3.3 **Event Capture / Largest**

If the Settings, Display: EMG View has the "Event Capture" button selected as the preference:
Selecting "Event Capture" from the Event Threshold block on the main display (see Section 6.4) "captures" EMG activity that exceeds the Event Threshold. The captured waveforms remain on the display until replaced by the next captured event.
If the Settings, Display: EMG View has the "Largest" button selected as the preference:
Selecting the "Largest" button causes the screen to display (statically) the largest event from a series of events. If, for example, the 3rd event from a series of 5 events measured over 4 seconds is the largest, it will be displayed on the screen under the text Largest/3 of 5. The 4 second timer restarts after each event, adding events to the total if they occur within the 4 seconds. If events occur greater than 4 seconds apart, each would be displayed as "Largest 1 of 1".
Note that neither Event Capture nor Largest are available when the X-axis time scale is set to 10 seconds (it is only available in the 50ms time scale).

## 7.4 Freeze

Pressing the "Freeze" button (when available on the display) causes the screen contents to be displayed, unchanged, until the next press of the Freeze button "unfreezes" the display. This is useful, not only to view an event over an extended period, but also to best enable a printout of the screen.

## 7.5 Quick Help

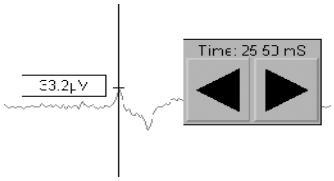
Pressing the "Quick Help" button will open the Quick Help Screen. A subsequent press on any menu or control item will then open a pertinent information screen.

## 7.6 Event Log

Selecting the Event Log option in the System Setting screen (see Sec. 6.5) will allow a history of all events to be printed/saved. At the end of (or during) a procedure, selecting the Print/Save button (depending on the output device selected) will result in all logged events being printed to the selected output device (printer or USB Compact Flash).
The event log is a continuous record of the last 300 events. At system startup, an event record is written to record baseline information. For example: During a particular case, 310 events occurred. At the end of the case, when the log is printed, it will contain the last 299 events, plus the baseline record that was recorded at startup.

## 7.7 View Event (Waveform Data)

= Amplitude and Time of an Event (Note: Event Capture **must** be on).
In the EMG display Area press directly on the event waveform you wish to measure. The amplitude will be displayed at the selected point. The time from zero (known as latency) will be displayed above the left/right increment buttons.
Time buttons will move the vertical line left or right in increments of 0.25 ms.
Voltage is read from 0 at Baseline to the value at the intersection of the vertical line.
Negative numbers (numbers below Baseline) appear with a minus sign in front of the value, where positive numbers have no character in front.
The cursors and displayed measurements will automatically turn off after 30 seconds of inactivity, or when another location is touched.



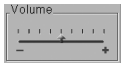

## 7.8 Output Device Button (Print or Save)

Depending on the output selected on the Systems Setting Screen (section 6.5) there will be either a "Print" or a Save button displayed on the appropriate screen.

***Pressing*** sends the current display, or the entire event log (if selected), as an image or text, to the Printer.

***Pressing*** sends the current display, or the entire event log (if selected), as an image or text, to the USB compact flash disk. Note: See your sales representative for further information on the correct CF Card and reader.

## 7.9 Volume Control

The  control adjusts the speaker/headphone volume. Upon Power Up, the VOLUME is automatically set at a moderate level (50%). The volume cannot be turned completely OFF (see Section 6.1.3 for further Volume information).

.

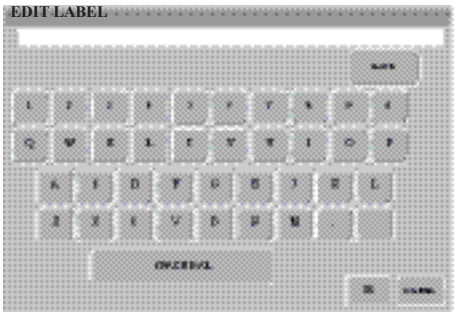
## 7.10 Edit a Channel Label (Recommended Montage Screen)

Press/Highlight


Press


Edit label keyboard will open.
Using keyboard enter alphanumeric characters until new label is complete. Press

channel will show new label




## 7.11 Electrode Placement Screen

This screen displays a range of electrode placement graphics, selectable by touching the buttons to the left of the screen. Connections are shown appropriately color coded, matching the recommended color-coded channels on the Patient Interface and on the electrodes themselves. Opposite is one of the screens available:

## 7.12 Recognizing Artifact

The NIM-Response® 2.0 features sophisticated artifact rejection technology designed to provide highly sensitive and accurate monitoring. However, there may be electrically generated signals in the range of true response that the NIM-Response® 2.0 cannot differentiate.
For example, a transcutaneous stimulator used by the anesthesiologist might generate an audible signal.
Another example would be any external nerve locator/stimulator not synchronized (Muting Probe) with the NIM-Response® 2.0.
Another possible source of electrical signal is electrical leakage from faulty thermal cautery units. You can identify the spurious signals by their lack of surgical context (there was nothing the surgeon was doing at that moment that could have caused a true EMG response).
If the recording electrodes and the stimulator (+) or (-) cables become tangled the resulting stimulus artifact might be spuriously detected as an EMG event. Be careful to route the recording electrodes away from stimulator cables.
There may also be interference-generated signals in the range of true response that the NIM-Response® 2.0 cannot differentiate. An example of this type of artifact signal could occur when the surgeon strikes two metal instruments together within the surgical field, such as a metal suction tube with a dissecting tool. Such signals are typically monophasic with fast onset and offset. That is, the signals appear on the screen as sharply peaked responses in one direction only.
While these artifacts are significantly different in waveform appearance from true EMG events (which have a biphasic waveform), the magnitudes of these signals can reach several hundred microvolts causing the event tone to sound. However, the surgeon is usually aware when two instruments have been struck together and can, therefore, relate such "false positive" responses to the surgical context.

## 7.13 Manufacturing Test

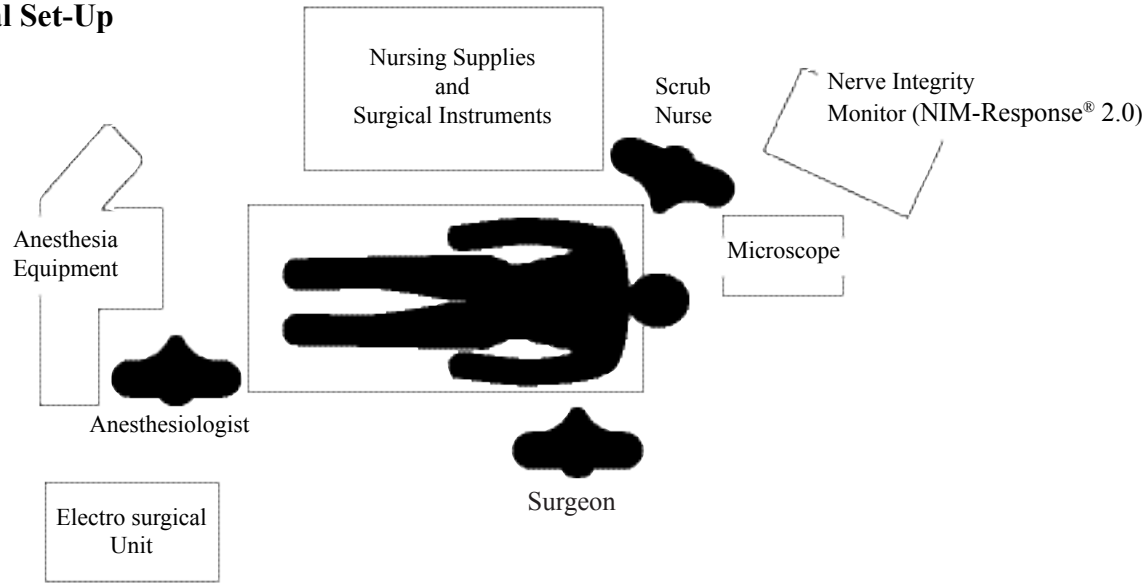
When following the instructions in section 4.2 regarding screen calibration, one of the two test option buttons is labeled "Manufacturing Test".
**The manufacturing test is not intended for end users and is to be used only under the direct supervision of Medtronic Xomed Personnel.**

## 8.0 OPERATING ROOM SET-UP

The NIM-Response® 2.0 Nerve Monitor has a few characteristics that need to be taken into consideration when setting up the O.R. Some of these characteristics include, but are not limited to, external devices, traffic patterns, sterile areas, color-coding, grounding, and muting detection.

Set the NIM-Response® 2.0 on a table or cart located about 10 feet from the surgical field but as far as possible from the electrosurgical unit. Also, consider traffic patterns and sterile areas. The surgeon may have further preferences as to location and visibility. **Please see Precautions P7, P10 and P6.**

## 8.1 Typical Set-Up




## 8.2 Recommended Patient Interface Set Up

Prior to surgery, the Patient Interface, Muting Probe and Stimulator **must** be setup. This may be done prior to the NIM-Response® 2.0 being turned on, or the NIM-Response® 2.0 may be used to support the process of determining which nerves to monitor, positioning the electrodes appropriately, and customizing the setup as needed to meet any special needs or preferences of the operating physician. See Sections 9 and 10 for further details.

The operating physician determines the particular nerves that are at-risk with each particular patient and procedure. The physician then places electrodes in the muscles innervated by the nerves at-risk. The electrode sites should be cleaned with alcohol to remove oils from the skin. The electrode needles are inserted into the patient, taped into position, and the wires routed away from where the surgeon will be working.

Clip the Patient Interface to the surgical bed near the head of the patient and within reach of the sterile electrode leads and sterile stimulator cable(s). Position it so that it is out of the way of the doctor and the scrub nurse. Attach the electrodes to the interface (see section 1.7).

Keep the Patient Interface cable and electrodes away from other equipment cords.

When wires must cross, they should cross at right angles. Never run operating room cords parallel to any of the NIM-Response® 2.0 wires.

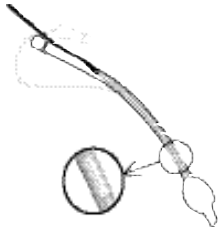
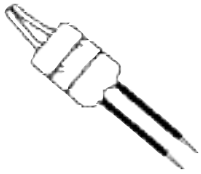
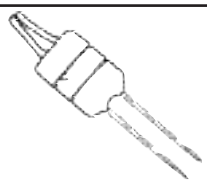
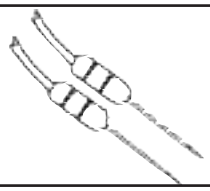
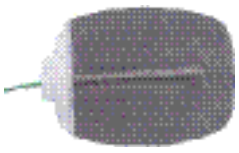
Lay the Patient Interface cable out of busy traffic patterns and secure it to the floor as needed.

## 8.3 Electrodes

Placement of electrodes should be performed by or under the direction of a licensed medical practitioner. Vigorous cleaning with an alcohol wipe or EEG lead prep pad should prep areas of electrode insertion. Usually, recording electrodes are placed before the sterile field is draped and defined. Never let electrode leads contact one another.

- Two electrodes per monitoring channel and one ground are required.
- The electrode pairs for each channel plug into color-coded input jacks on the patient interface.
- Route the white (+) stimulus return wire (monopolar) away from the channel 1-4 electrode wires.
- If/when wires must cross; they should cross at right angles. Never run other operating room cords/cables parallel to any of the NIM-Response® 2.0 wires.
- Verify the electrodes are properly inserted by turning on the NIM-Response® 2.0 and looking at the Electrode screen. This may determine if electrodes need to be re-inserted for better electrical contact to help optimize monitoring.

  Please review **Warning W16 and Precaution P9** regarding electrode placement.

| Electrode types recommended for use with the NIM-Response® 2.0 System | | | |
|---|---|---|---|
| **Electrode** | **Description** | **Electrode** | **Description** |
|  | EMG Endotracheal Tube<br>Two stainless steel contact electrodes designed to monitor both vocal cords. | | Prass Paired Electrodes<br>The electrodes are insulated to within 5 mm of the end with 5 mm spacing.<br>Muscle-specific single use |
| | Hookwire Electrode<br>Two small wires attached to the end of a hypodermic needle. Injected intramuscularly (then the hypo is removed) The wires are insulated to within 3 mm of the end and are designed to obtain a more specific response. |  | Prass Paired Electrodes Small Hub<br>The electrodes are insulated to within 5 mm of the end with 2.5 mm spacing.<br>Muscle-specific single use. |
|  | Paired Subdermal Electrodes<br>Non-insulated high performance electrodes with 2.5 mm spacing |  | Subdermal Needle Electrodes<br>Non-insulated high performance electrodes 12 mm long with a 0.4 mm diameter. |
|  | Ground Pad Electrode. | | Ground Needle Electrode. |

**Ground**

All monitoring electrodes use a single ground electrode (color-coded green).

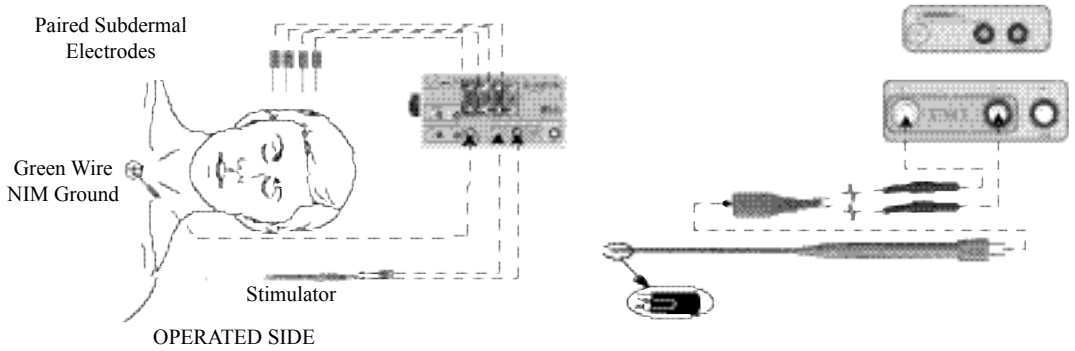
Always locate the ground in a non-innervated, electrically neutral area (electrically neutral areas are where the bone is close to the skin and the electrode will not contact muscle tissue). Ground should also be located between the stimulator and monitoring electrodes (see illustrations on the next page).

## 8.4 Stimulator

The NIM-Response® 2.0 Stimulator output supports the use of both monopolar and bipolar stimulating probes with a range of 0-30 mA. **Please see Warning W7.**

8.4.1 **Bipolar Probe and Cable:**

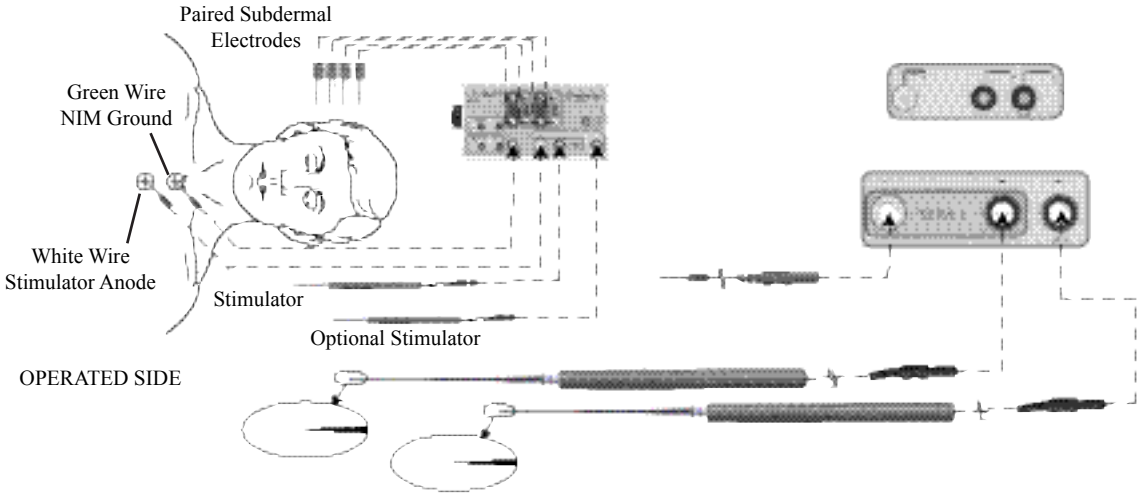
When bipolar stimulation is required, only one probe can be used. The stimulator connection uses two different diameter pins to connect to the cable. The cable to patient interface uses color-coded connectors (white wire with a red plug, connecting to the white jack (+) with a red ring, and black plug connecting to the black (-) jack). The black AUX (-) jack cannot be used in this application.



8.4.2 **Monopolar Probe and Universal Handle:**

Patient interface supports one or two single use probes. The handle plug is color-coded black and plugs into the black (-) jack on the patient interface. The monopolar-stimulating probe delivers current to the patient and acts as the cathode.

The white electrode (+) is required for monopolar stimulation. It is referred to as the stimulus return or anode. Plug the red connector of the white electrode into the white jack with a red ring (+). Route the white (+) stimulus return wire away from the channel 1-4 electrode wires.




## 8.5 Muting Probe Set up

See Section 7.2 for the required details of muting probe set up.

## 8.6 Anesthesia Requirements

All decisions regarding anesthesia are the responsibility of the attending licensed medical practitioner administering the anesthesia. Because all intraoperative monitoring discussed in this User's Guide requires that EMG activity be recorded from a muscle or muscles, it is important that the muscle(s) not be paralyzed during the surgery or at least during those parts of the surgery when the nerve(s) being monitored is (are) deemed at risk by the surgeon. It is important that the surgeon discuss these issues preoperatively with the attending licensed medical practitioner administering the anesthesia.

**Note the following Contraindication for Use:**

**The use of paralyzing anesthetic agents will significantly reduce, if not completely eliminate, EMG responses to direct or passive nerve stimulation. Whenever nerve paralysis is suspected, consult an anesthesiologist.**

**Warning**

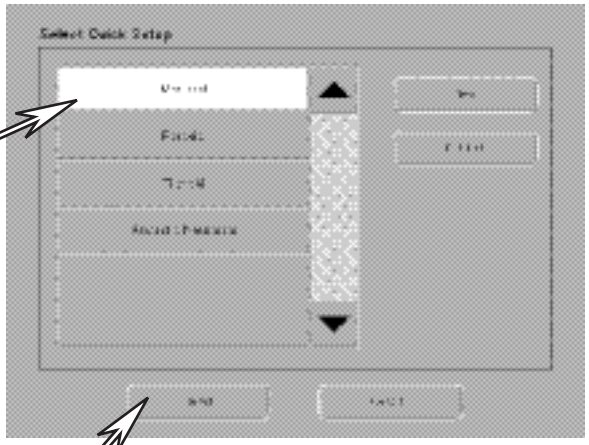
W10 To avoid the risk of fire or explosion, do not use the NIM-Response® 2.0 in the presence of flammable anesthetics and/or oxygen rich environments.

## 9.0 HOW TO MONITOR

The NIM-Response® 2.0 has a large number of user selectable characteristics used during a typical setup procedure. This section will address the two most common types of setup procedures.
First the "STANDARD" Setup that uses a factory loaded program (Mastoid will be used for explanation purposes) The second type is a "CUSTOM" Setup. This allows the surgeon to define the surgery being performed and the nerves to be monitored. In this section for explanation purposes, the surgeon is to remove a Glomus Tumor and wishes to monitor Cranial Nerve X (muscle groups Left and Right Vocalis) and Cranial Nerve XI (muscle groups Trapezius and Sternomastoid).
**Please review Warnings W1, W13, W16, W18 and W19.**

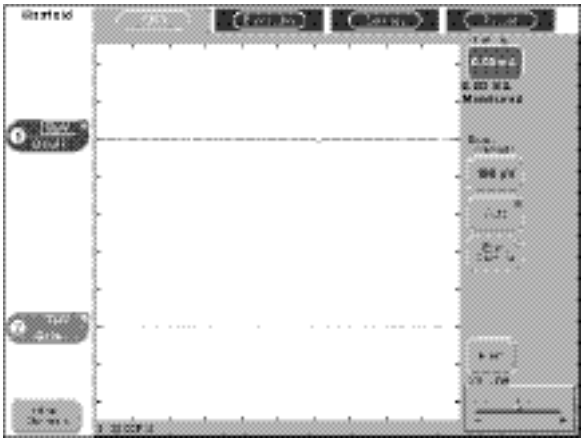
## 9.1 Standard Set-Up (Using "Mastoid" as an example)

**QUICK SETUP SCREEN**



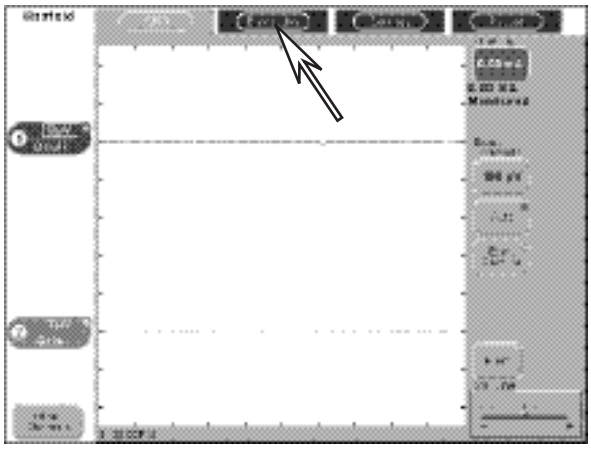

1. Press/highlight a setup.
2. Press select.

NOTE Mastoid will be used through out this manual except for "Custom Setup".



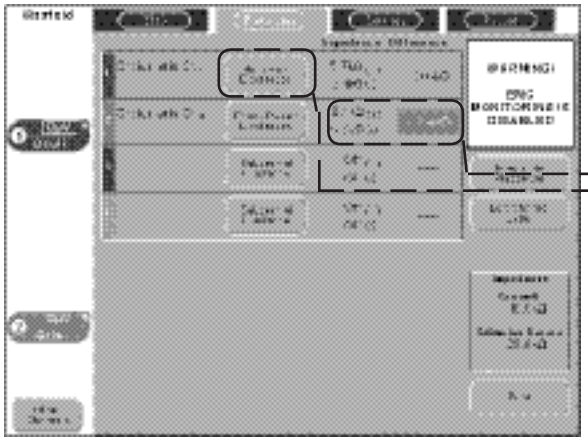
Current screen should show:

- Channels 3 and 4 are turned off.
- Additional (Other Channels) button.
- Only basic display features are selected.



1. Change to Electrodes Screen.

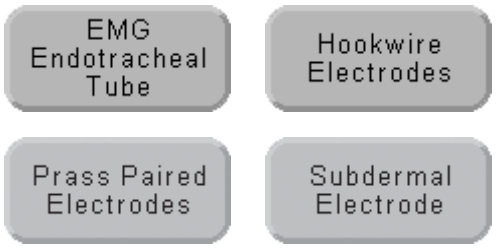
**ELECTRODES SCREEN**



- Select the appropriate electrodes (the standard electrodes are shown)
- Check the positive and negative impedance of connected electrodes.
- Check the difference in their values. If the result is out of the range for the selected electrode, the number will be highlighted in red.
- Check the impedance of the green ground electrode.
- Check the impedance of the white stimulus electrode (anode).
- Close the electrode screen and return to monitoring by pressing the EMG tab.
- If you wish to use, or view, the Electrode Placement graphics press the "Electrode Placement" button – see Section 7.10 for details. Otherwise, close the screen and return to monitoring by pressing the EMG tab.

Example of "Failed Difference"

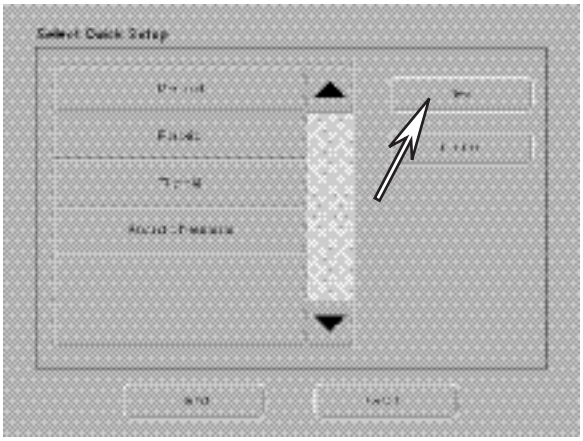
Electrode types




| ELECTRODE TROUBLESHOOTING | | |
|---|---|---|
| **SYMPTOM** | **CAUSE** | **SOLUTION** |
| Electrode impedance is too high.<br>> 10 KΩ for subdermal electrodes<br>> 10 KΩ for EMG tube | Electrode dislodged from patient, but not completely out.<br>High resistance in electrode.<br>Electrode pin not firmly inserted into patient interface. | Insert dislodged electrode; tape down in place.<br>Remove and replace with new electrode.<br>Check connection at Patient Interface box. |
| Electrode impedance equals 0.0 KΩ | Positive and negative electrodes touching below surface of skin.<br>Extremely low impedance, particularly in EMG tubes. | Remove and relocate electrodes. |
| Channel button is flashing.<br>Electrode reading is "—KΩ" or "OFF." | Electrode laying on skin surface.<br>Electrode placement insecure.<br>Dirty electrode tip.<br>Electrode cable is broken.<br>Electrode pin disconnected from patient interface. | Re-insert electrode in question.<br>Remove and replace electrode in question.<br>Check connection to Patient Interface box. |

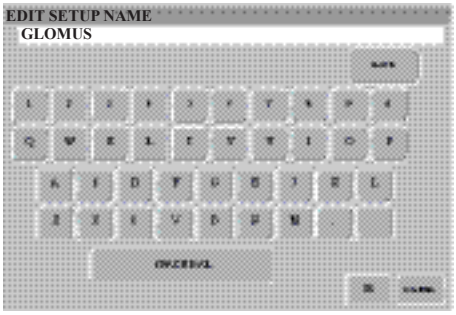
## 9.2 Custom Set-Up

In this section the surgeon is to remove a Glomus Tumor and wishes to monitor Cranial Nerve X (muscle groups Left and Right Vocalis) and Cranial Nerve XI (muscle groups Trapezius and Sternomastoid).

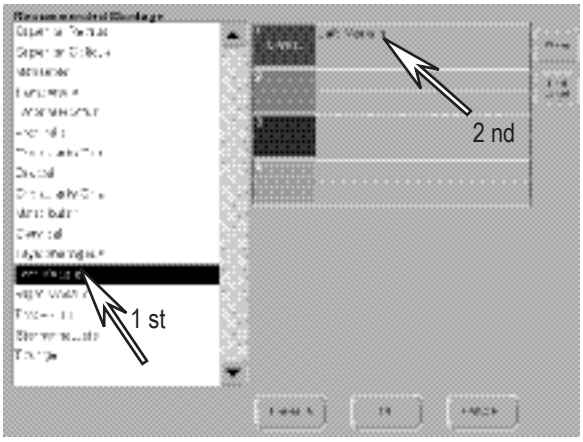


1. From the default Quick Setup screen, select "New".

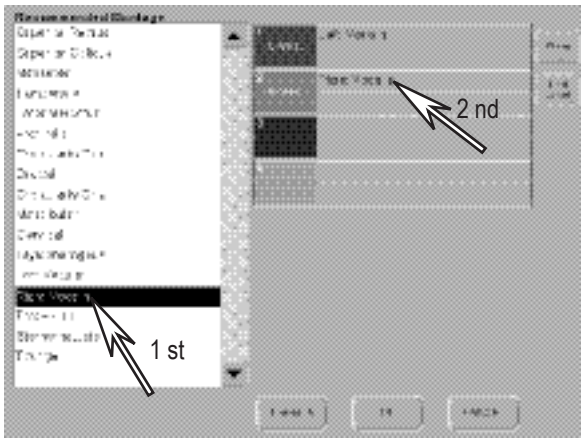
**EDIT SETUP KEYBOARD**



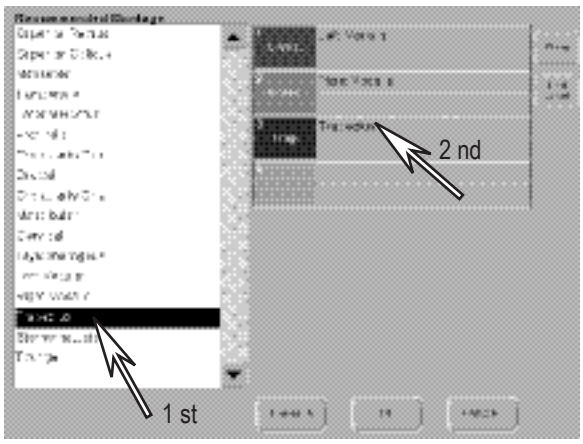

1. Default name (SETUP #) will open.
2. Use backspace to remove default name and enter new name.
   Note: 32 characters total.
3. Press OK to accept new setup name.



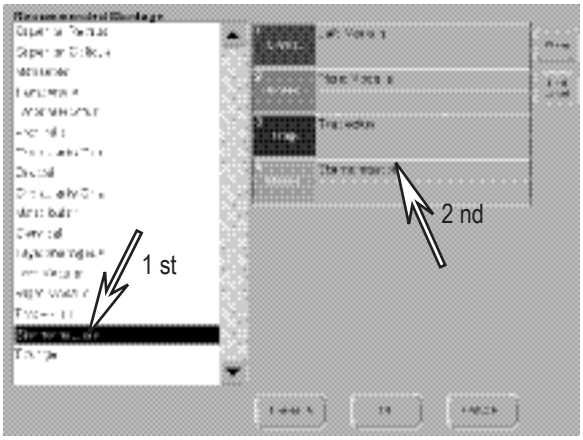

1. Highlight the desired muscle group to monitor.
2. Load channel 1 by pressing top half of gray bar.



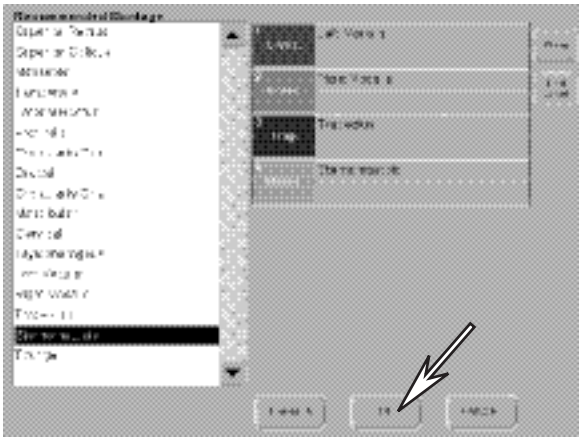

Highlight second desired group, Load Channel 2.



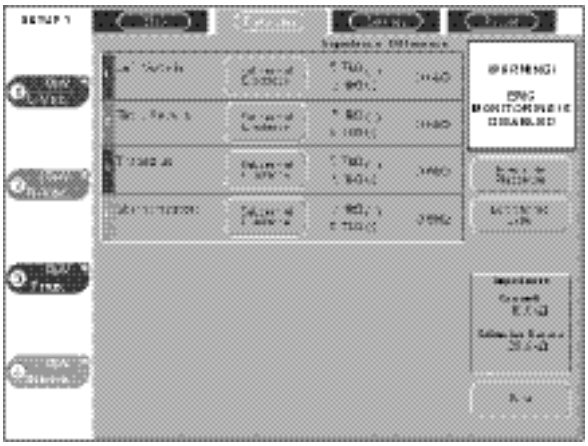

Highlight third desired muscle group, Load Channel 3.




Load channel 4.



Press OK to Exit Montage Screen.



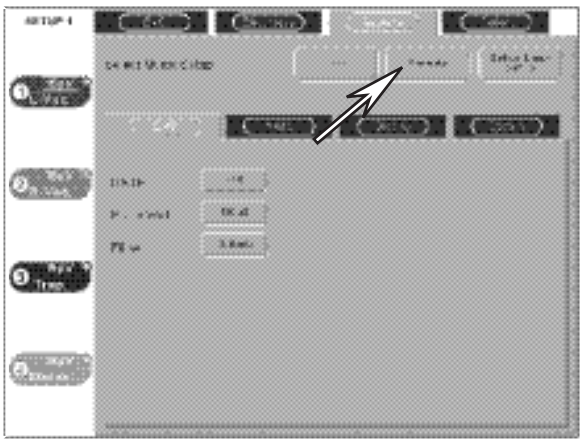
- Select electrodes for each channel.
- Check the positive and negative impedance of connected electrodes.
- Check the difference in their values.
- Check the impedance of the green ground electrode.
- Check the impedance of the white stimulus electrode (anode).

If you wish to save your setup,

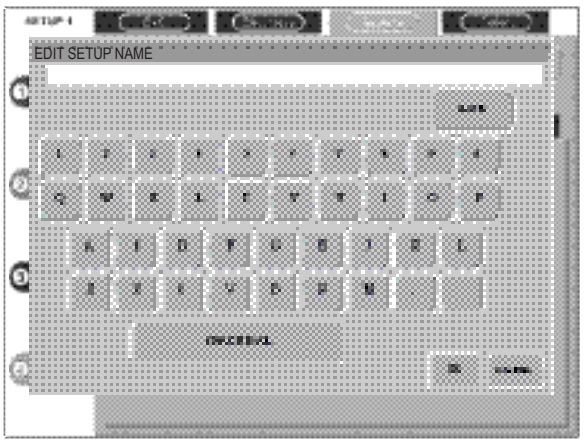
- Change screen to Settings.
- Go to next illustration… (Section 9.3).

Note: if you wish to use, or view, the electrode placement graphics press the “electrode placement” button – see section 7.11 for details.

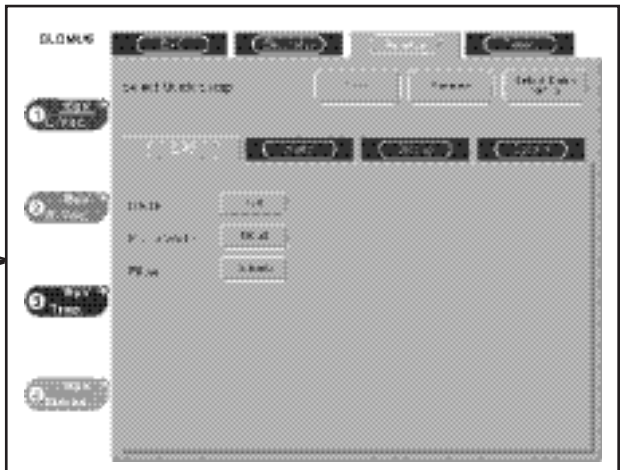
## 9.3 Saving a Set-Up



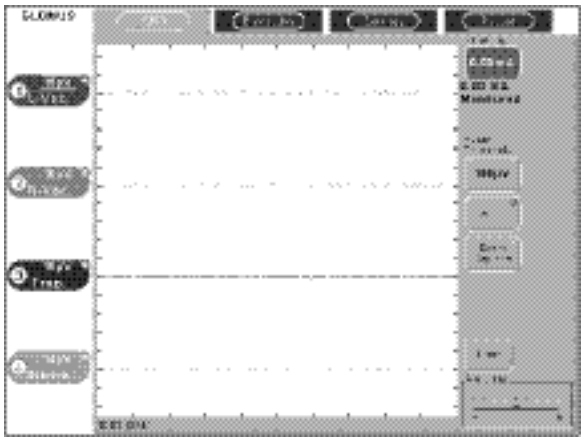
Starting at Settings Screen – Select “Save As”.




1. Use backspace to remove default name and enter (GLOMUS as this example) new name.
   Note: 32 characters total.
2. Press OK to accept new setup name.



At this point you have completed your Custom Setup and should proceed to the EMG Screen for monitoring.
Press the “EMG” tab to return to monitoring.



***Main Display***

# 10 CLEANING AND MAINTENANCE

## 10.1 Cleaning (after each use)

- Disconnect the power of the NIM-Response® 2.0 or printer before cleaning. **Please see Additional Precaution AP2.**
- Disconnect all cabling from rear of NIM monitor.
- Wipe the patient interface and cable, muting probe and cable(s), printer cable, printer, power cords, headphones, USB compact flash, and the NIM monitor console with a soft cloth that has been **dampened** with disinfectant or mild detergent and water.
- To prevent cleaning solutions from seeping into the electronic portions of the instrument and interfaces, spray cleaner lightly on a cotton cloth, then wipe the instrument and interfaces with the cloth. Be especially careful around the controls, connectors and panel edges.
- **Do not** use abrasive cleaners (especially on the touch screen).
- Visually inspect for damage.
  (Note that only qualified Medtronic Xomed service personnel should replace damaged parts.)

## 10.2 Fuses

The console AC power is fuse protected. Have a Biomedical Engineer check the fuse if a problem is suspected. It is very important that the correct replacement fuse is used (5 x 20mm, 4Amp, 250V, Quick-acting, Low breaking capacity, Xomed Part # 8250614).

The Patient Interface has its own fuse. See the fuse kit insert for details on how to check and replace this fuse. It is very important that the correct fuse is used – It **must be** Xomed Part # 8250615 (similar 32mA Type F, 250V 5 x 20 mm fuses may not offer the same degree of protection).

## 10.3 Storage

- Allow the NIM-Response® 2.0 and accessories to thoroughly air-dry before storing in a cool dry place.

## 10.4 Service and Repair Procedures

Medtronic Xomed is committed to provide the highest standard of workmanship in manufacturing its products. Your NIM-Response® 2.0 requires minimal maintenance and calibration. However, Medtronic Xomed recommends preventative maintenance and screen calibration scheduled at yearly intervals(See Appendix B). **Please see Additional Precaution AP3.** Comprehensive testing and calibration should be performed by returning the entire system, including the patient interface and muting probe to Medtronic Xomed Customer Service. Contact them directly (see Section 2 for contact numbers and addresses) for details of how to return your product.

## 11.0 TROUBLESHOOTING

| SYMPTOM | CAUSE | SOLUTION |
|---|---|---|
| No visual display or audio alarms at power-up. | Power cord not connected to outlet or to the NIM-Response® 2.0 system.<br>Power switch not turned on. | Plug in power cord.<br>Turn power switch on |
| Touching the screen has unexpected results. | Touch screen out of calibration. | Turn unit off and back on; immediately press and hold the screen until the screen calibration test is displayed. Follow the instructions on the screen to recalibrate |
| Electrode impedance is too high.<br>> 10 K Ù for subdermal electrodes<br>> 25 K Ù for Prass paired electrodes<br>> 10 K Ù for EMG tube<br>> 40 K Ù for hookwire electrode | Electrode dislodged from patient, but not completely out.<br>High resistance in electrode.<br>Electrode pin not firmly inserted into patient interface. | Insert dislodged electrode; tape down in place.<br>Remove and replace with new electrode.<br>Check connection at Patient Interface box. |
| Electrode impedance equals 0.0K Ù | Positive and negative electrodes touching below surface of skin.<br>Extremely low impedance, particularly in EMG tubes. | Remove and relocate electrodes.<br>Use “tap test” near electrodes to evoke EMG or artifact (increase threshold, decrees volume for test). If activity is noted on channel in question, proceed. |
| Channel button is flashing.<br>Electrode reading is “—K Ù” or “OFF.” | Electrode laying on skin surface.<br>Electrode placement insecure.<br>Dirty electrode tip.<br>Electrode cable is broken.<br>Electrode pin disconnected from patient interface. | Re-insert electrode in question.<br>Remove and replace electrode in question.<br>Check connection to Patient Interface box. |
| Electrode difference is greater than 2 K Ù (Subdermal electrodes) or 10K Ù (Prass Paired electrodes). | Dirty electrode.<br>Mismatched pair.<br>Unequal placement. | Remove and replace electrode for appropriate channel with highest impedance reading first.<br>Remove and replace electrode in question. |
| Electrosurgical interference. | Muting Probe not connected.<br>Muting Probe input insufficient.<br>Electrosurgical grounding inadequate.<br>Source of interference unidentified.<br>NIM-Response® 2.0 system or Patient Interface cable too close to electrosurgical unit or its cables. | Check Muting Probe connections.<br>Move input to “MORE MUTE”.<br>Check electrosurgical grounding pad on patient.<br>Identify source of interference; then eliminate or separate from the NIM-Response® 2.0 system.<br>Maintain separation between electrosurgical cable and the NIM-Response® 2.0system.<br>For less coupling, coil up the Muting Probe next to the NIM-Response® 2.0 system. |
| Interference on anesthesia equipment (EKG Monitor) | Measuring current on NIM EMG Electrodes<br>Electrode Check (Electrode Screen selected)<br>Muting function active.<br>With Stimulator active. | Try an alternate EKG Lead set.<br>Close/deselect Electrode Screen.<br>See Excessive Muting (Symptom Column).<br>Turn the NIM Stimulator to 0.0 mA when not needed. |
| Excessive Muting | Unit receiving excessive signal into the Muting Probe or electrode leads. | Move the Muting Probe connector to a lower number unit until it stops muting. If it still mutes in position “1”, disconnect the muting detector completely. |

| SYMPTOM | CAUSE | SOLUTION |
|---|---|---|
| Inadequate muting. | Signal from electrosurgical unit inadequate to cause muting. | Move the Muting Probe connector to a higher number until it mutes. If it still does not mute in position "4", loop the electrosurgical unit cable and clip the muting detector over the doubled cable. |
| No response to direct stimulation | Inadequate stimulus intensity. | Increase stimulus intensity. |
| | Paralyzing anesthetic in use. | Eliminate paralyzing anesthetic. |
| | White Stimulation (+) electrode has fallen out or is not connected. | Check that Stimulus Measure is approximately the same value as the Stimulus setting. Re-insert electrode in question. |
| | Probe (electrode) not connected. | Check stimulator anode (+) and cathode (-) connections. |
| | Patient safety fuse blown.<br>STIM 1 (EMG) Patient Interface fuse REF 8250615 | Check fuse in STIM 1 (EMG) Patient Interface Replace if necessary. |
| | Not holding probe on nerve long enough. | Hold probe tip to nerve for at least 1 second. |
| | Nerve not contacted. | Check stimulator tip for obstruction. Replace if necessary. Check location of stimulation. |
| | Volume control too low.<br>Event threshold set too high. | Check and correct all settings: volume, event threshold, stimulus intensity. |
| | Excessive current shunting in surgical field. | Remove fluids from surgical stimulating area. |
| | No electrodes in innervated muscle tissue. Nerve not stimuable. | Place channel electrodes in muscle to be monitored. |
| Unexpected responses when not directly stimulating nerve. | Unexplained continuous "train" EMG response. | Identify and eliminate possible source of "train" stimulation:<br>Cold irrigation.<br>Laser heat.<br>Retraction on nerve or muscles being recorded.<br>Patient waking from anesthesia.<br>Nerve drying.<br>Ultrasonic aspirator.<br>Identify and eliminate source of inadvertent manipulation. |
| | Nerve or monitoring area being stimulated or manipulated by thermal or mechanical means. | Determine response type from waveform pattern on 50 ms screen. |
| | Metal-to-metal discharge artifact. | Disentangle recording electrode and stimulator cables. |
| | Intertwined recording electrode and stimulator wires. | Check area near recording electrodes for excessive stretching from tape, drapes, etc. |
| | Inadvertent manipulation of electrode wires, Patient Interface cable, or recording area on patient. | Check for intermittent stimulation from anesthesiologist (i.e., hand-held electrical stimulator). |
| | Electrical interference from other equipment. | Move NIM-Response® 2.0 system away from source of interference.<br>Make sure Patient Interface cable and electrode wires do not cross other electrical equipment or cables. |

## 12.0 TECHNICAL SPECIFICATIONS

**Physical Dimensions**

| | |
|---|---|
| Size: | 31 cm W x 27 cm H x 37 cm D |
| Weight: | 8.5 Kg |

**Operational Environment**

| | |
|---|---|
| Operating Temperature range: | 10 to 40º C (Operating) |
| Humidity: | 5-95% RH non-condensing |

**Transport and Storage Environment**

| | |
|---|---|
| Ambient Temperature range: | - 40 °C to + 70 °C |
| Relative Humidity range: | 10 % to 100 %, including condensation |
| Atmospheric Pressure range: | of 50 kPa to 106 kPa |

**Amplifier**

| | |
|---|---|
| Channels – 1 to 4: | Individually and simultaneously selectable. |
| Input Sensitivities: | 5 – 10000 µV peak-to-peak AC-coupled, |
| Sensitivity Selection: | Automatically zeroed |
| Bandpass: | 100 Hz - 2 kHz EMG Display<br>200 Hz - 3.2 kHz Audio EMG Speaker |
| Input Noise: | 5-11 µV p-p < 3 µV RMS @ DC - 4 Hz, inputs shorted |
| Input Impedance | > 200 K Ohm ± 10% |
| DC offset Rejection | ± 0.540 V DC Rejection |
| Common Mode Rejection: Ohm imbalance | >90 dB @ 60 Hz, balanced inputs, >70 dB @ 60 Hz, 1 K |
| Channel Enable/Disable Controls: | Dedicated function touchpads for independent channel enable/disable. |
| Event Threshold Control and Display: | Adjustable Graduated Touch Bar with Voltage threshold displayed. |
| Patient Isolation | 1000 Vrms 60 Hz < 100 µA |

**Impedance Measurement**

| | |
|---|---|
| Control: | Automatic CHECK ELECTRODE feature. |
| Measuring Signal: | 20 µA peak-to-peak, 60 Hz Square wave. |
| Measurement Range: | 0-200 K Ohm ± 10% |

**Artifact Detection and Rejection**

| | |
|---|---|
| Stimulus Artifact: | Synchronized and adjustable muting. |
| Electrocautery Interference: | Automatic detection, muting and warning. |
| Electrode Lead Off: | Automatic detection, muting and warning. |

**Display / Touch Screen**

| | |
|---|---|
| Type: | High contrast, digital, graphic Color, visible in complete darkness. |
| Resolution: | Display 600H x 800W pixels, Touch Panel 256H x 256W |
| Dedicated Function Event Touch Screen Controls: | For Amplitude, Time Display and Capture. |
| Vertical Display: | 50, 200, 500 and 2000 µV display modes. |
| Event Capture: | Enable/disable capture mode indicator on touch screen. |
| Time Scale: | 50ms or 10s display modes. |

**Stimulator**

| | |
|---|---|
| Stimulus Type Constant: | Constant Current |
| Stimulus Range: | 0-30 mA, maximum 120 V compliance |
| Stimulus Control: | Digitally controlled, range – dependent adjustment increments of .01, .05, 1.0 and 5.0 mA. |
| Stimulus Output Accuracy: | ± .02 mA (or ± 5% of reading at 1K load) over Stimulus Range. |
| Stimulus Adjustment: | Graduated Touch Screen Control with display of command current and delivered current. |
| Stimulus Measurement Accuracy | ± .02 mA (or ± 5% of reading at 1K load) over Stimulus Range. |
| Internal Fuse | 32 mA Type F, 250V 5 x 20mm (**It must be Xomed # 8250615**, other similar fuses may not give the same degree of protection. |

Order 8250615 Fuse Kit for replacements. **See Precaution P16**

**Stimulus Characteristics**

| | |
|---|---|
| Waveform: | Monophasic, square pulse |
| Duration: | Software selectable, 50, 100, 150, 200 or 250 µs |
| Rise Time: | Less than 20 µs |
| Rate: | Software selectable, 1, 4, 7, or 10 Hz |
| Stimulus Probe: | Monopolar (standard) or bipolar |

**Audio Output**

| | |
|---|---|
| Transducers: | Built-in 4.0 x 6.0 inch speaker |
| EMG & Event Tone Signals: | Continuously processed EMG and/or activity-level dependent event tones for each channel. |
| Volume Preset and Limiter: | Volume Power Up Pre-set Default and a Low Volume Limiter. |
| "Current Delivered" Tone Signals: | Selectable options include continuous and brief warble tone, voice and voice setting. Signal occurs when 80% of set current is measured over range of .05-30 mA. |
| Connection: | RCA Phone Jack |
| Headphones: | Impedance @1 KHz is 25 Ohm or greater SPL 107 ± 4 dB. Plug 3.5 mm Stereo Nickel Plated |

**I / O - Printer Output / Disk Drive Output**

| | |
|---|---|
| Printer Interface: | Hewlett-Packard: Model: DeskJet 5650 printer. |
| Connection: | Centronics Parallel 36-pin female or USB (2) |

**Video Output**

| | |
|---|---|
| Interface: | VGA Compatible, 800 x 600 resolution |
| Connection: | 15-pin HD |

**Electrical**

| | |
|---|---|
| Input Voltage | 100V, 120V, 220V, and 230-240V ± 10% |
| Frequency | 50/60 Hz |
| Power Consumption: | 47 W Nominal, <70 W Peak |
| Auxiliary AC output: | 250 VA Max. |
| Line Isolation: Connections to Signal Ground | 4000 V Peak-to-Peak 60 Hz dielectric withstand from Line |
| Internal Fuse | 5 x 20mm, 4Amp, 250V, Quick-acting, Low breaking capacity, Xomed Part # 11270037. Order 8250614 Fuse Kit for replacements. |
| Patient Connections | All patient probes and electrodes are Type BF M Applied Parts. |
| Class 1:1988/A1:1992/A2:1995/A:13:1995 | Class I Medical Device per EN 60601 |

## 13.0 Guidance and manufacturer's declaration – electromagnetic immunity and emissions

| Guidance and manufacturer's declaration – electromagnetic immunity Part I | | | |
|---|---|---|---|
| The NIM-Response® 2.0 is intended for use in the electromagnetic environment specified below. The customer or the user of the NIM-Response® 2.0 should assure that it is used in such an environment. | | | |
| **Immunity test** | **IEC 60601 test level** | **Compliance level** | **Electromagnetic environment - guidance** |
| Electrostatic discharge (ESD)<br><br>IEC 61000-4-2 | ±6 kV contact<br><br>±8 kV air | ±6 kV contact<br><br>±8 kV air | Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %. |
| Electrical fast transient/burst<br><br>IEC 61000-4-4 | ±2 kV for power supply lines<br><br>±1 kV for input/output lines | ±2 kV for power supply lines<br><br>±1 kV for input/output lines | Mains power quality should be that of a typical commercial or hospital environment. |
| Surge<br><br>IEC 61000-4-5 | ±1 kV differential mode<br><br>±2 kV common mode | ±1 kV differential mode<br><br>±2 kV common mode | Mains power quality should be that of a typical commercial or hospital environment. |
| Voltage dips, short interruptions and voltage variations on power supply lines<br><br>IEC 61000-4-11 | <5 % UT for 0.5 cycle<br><br>40 % UT for 5 cycles<br><br>70 % UT for 25 cycles<br><br><5 % UT for 5 sec | <5 % UT for 0.5 cycle<br><br>40 % UT for 5 cycles<br><br>70 % UT for 25 cycles<br><br><5 % UT for 5 sec | Mains power quality should be that of a typical commercial or hospital environment. If the user of the NIM-Response® 2.0 requires continuous operation during power mains interruptions, it is recommended that the NIM-Response® 2.0 be powered from an uninterruptible power supply or a battery. |
| Power frequency (50/60 Hz) magnetic field<br>IEC 61000-4-8 | 3 A/m | 3 A/m | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. |
| Note: UT is the a.c. mains voltage prior to application of the test level. | | | |

## Guidance and manufacturer's declaration – electromagnetic emissions

The NIM-Response® 2.0 is intended for use in the electromagnetic environment specified below.
The customer or the user of the NIM-Response® 2.0 should assure that it is used in such an environment.

| Emissions test | Compliance level | Electromagnetic environment - guidance |
|---|---|---|
| RF emissions<br>CISPR 11 | Group 1 | The NIM-Response® 2.0 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. |
| RF emissions<br>CISPR 11 | Class B | The NIM-Response® 2.0 is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings for domestic purpose. |
| Harmonic emissions<br>IEC 61000-3-2 | Class A | |
| Voltage fluctuations<br>IEC 61000-3-3 | Complies | |

## Recommended separation distances between portable and mobile RF communications equipment and the NIM-Response® 2.0

The NIM-Response® 2.0 is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the NIM-Response® 2.0 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the NIM-Response® 2.0 as recommended below, according to the maximum output power of the communications equipment.

| Rated maximum power of transmitter<br>W | Separation distance according to frequency of transmitter (meters) | | |
|---|---|---|---|
| | **150 kHz to 80 MHz**<br>$d = 1.2\sqrt{P}$ | **80 MHz to 800 MHz**<br>$d = 1.2\sqrt{P}$ | **800 MHz to 2.5 GHz**<br>$d = 2.3\sqrt{P}$ |
| 0.01 | 0.12 | 0.12 | 0.23 |
| 0.1 | 0.38 | 0.38 | 0.73 |
| 1 | 1.2 | 1.2 | 2.3 |
| 10 | 3.8 | 3.8 | 7.3 |
| 100 | 12 | 12 | 23 |

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.
NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

## Guidance and manufacturer's declaration – electromagnetic immunity Part II

The NIM-Response® 2.0 is intended for use in the electromagnetic environment specified below.
The customer or the user of the NIM-Response® 2.0 should assure that it is used in such an environment.

| Immunity test | IEC 60601 test level | Compliance level | Electromagnetic environment - guidance |
|---|---|---|---|
| | | | Portable and mobile RF communications equipment should be used no closer to any part of the NIM-Response® 2.0, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.<br><br>**Recommended separation distance** |
| Conducted RF<br>IEC 61000-4-6 | 3 Vrms<br>150 kHz to 80 MHz | 3 Vrms | $d = 1.2\sqrt{P}$ |
| Radiated RF<br>IEC 61000-4-3 | 3 V / m<br>80 MHz to 2.5 GHz | 3 V / m | $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz<br>$d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz<br><br>where $P$ is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and $d$ is the recommended separation distance in meters (m).<br>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b]<br>Interference may occur in the vicinity of equipment marked with the following symbol: |

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the NIM-Response® 2.0 is used exceeds the applicable RF compliance level above, the NIM-Response® 2.0 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the NIM-Response® 2.0.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

## 14.0 LIMITED WARRANTY

A This LIMITED WARRANTY provides assurance for the customer who purchases a NIM-Response® 2.0 (hereinafter the "Product") that should the Product fail to function to Medtronic Xomed's published specifications during the term of this LIMITED WARRANTY (one year from the date of shipment for new Product, 90 days from date of shipment for refurbished or used Product), Medtronic Xomed will either replace, repair, or issue a credit (adjusted to reflect the age of the Product) for the Product or any portion thereof. This LIMITED WARRANTY is extended only to the buyer purchasing the Product directly from Medtronic Xomed or from its affiliate or its authorized distributor or representative.

B. To qualify for this LIMITED WARRANTY, the following conditions **must** be met:
(1) The Product **must** be used on or before its "Use By" or "Use Before" date, if applicable.
(2) The Product **must** be used in accordance with its labeling and may not be altered or subjected to misuse, abuse, accident or improper handling.
(3) Medtronic Xomed **must** be notified in writing within thirty (30) days following discovery of a defect.
(4) The Product **must** be returned to Medtronic Xomed within thirty (30) days of Medtronic Xomed receiving notice as provided for in (3) above.
(5) Upon examination of the Product by Medtronic Xomed, Medtronic Xomed shall have determined that: (i) the Product was not repaired or altered by anyone other than Medtronic Xomed or its authorized representative, (ii) the Product was not operated under conditions other than normal use, and (iii) the prescribed periodic maintenance and services have been performed on the Product.

C. This LIMITED WARRANTY is limited to its express terms. **THIS LIMITED WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED WHETHER STATUTORY OR OTHERWISE, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.** In no event shall Medtronic Xomed be liable for any consequential, incidental, prospective or other similar damage resulting from a defect, failure, or malfunction of the Product, whether a claim for such damage is based upon the warranty, contract, negligence or otherwise.

D. The exclusions and limitations set out above are not intended to, and should not be construed so as to, contravene mandatory provisions of applicable law. Users may benefit from statutory warranty rights under legislation governing the sale of consumer goods. If any part or term of this LIMITED WARRANTY is held by any court of competent jurisdiction to be illegal, unenforceable, or in conflict with applicable law, the validity of the remaining portion of the LIMITED WARRANTY shall not be affected, and all rights and obligations shall be construed and enforced as if this LIMITED WARRANTY did not contain the particular part or term held to be invalid.

**CAUTION**

Applicable law may restrict the sale, distribution or use of this device to, by or on the order of a licensed medical practitioner.

## Appendix A: NIM-Response® 2.0 System Components & Accessories

(See Medtronic Xomed Catalog for product details)

| | |
|---|---|
| 8252001 | NIM-Response® 2.0 Console |
| 8252200 | NIM-Response® 2.0 Patient Interface |
| 8252600 | NIM-Response® 2.0 Patient Simulator |
| 8250614 | NIM-Response® 2.0 Console Fuse Kit |
| 8250615 | NIM-Response® 2.0 Patient Interface Fuse Kit |
| 8252111 | NIM Printer System Kit |

**EMG ENDOTRACHEAL TUBES**

| | |
|---|---|
| 8229306 | EMG Endotracheal Tube Reinforced 6mm/Protected pin |
| 8229307 | EMG Endotracheal Tube Reinforced 7mm/Protected pin |
| 8229308 | EMG Endotracheal Tube Reinforced 8mm/Protected pin |

**MONOPOLAR STIMULATING PROBES**

| | |
|---|---|
| 8225101 | Standard Prass Flush-Tip Stimulator Probe, 5/Box |
| 8225110 | Standard Prass Flush-Tip Stimulator Probe, 10/Box |
| 8225103 | Slim Prass Flush-Tip Stimulator Probe, 5/Box |
| 8225105 | Slim Prass Flush-Tip Stimulator Probe, 10/Box |
| 8225275 | Ball-Tip Monopolar Stimulator Probe 1mm, 1/Box |
| 8225276 | Ball-Tip Monopolar Stimulator Probe 2.3mm, 1/Box |
| 8225278 | Ball-Tip Monopolar Stimulator Probe 1mm, 10/Box |
| 8225277 | Ball-Tip Monopolar Stimulator Probe 2.3mm, 10/Box |
| 8225251 | Yingling Flex-Tip Monopolar Stimulating Probe, 5/Box |
| 8225051 | Monopolar Stimulator Handles, 10/Box |

**BIPOLAR STIMULATING PROBES**

| | |
|---|---|
| 8225351 | Concentric Bipolar Stimulating Probe, 5/Box |
| 8225401 | Side By Side Bipolar Stimulating Probe, 5/Box |
| 8225451 | Prass Bipolar Stimulator Probe, 5/Box |

**POWER CORDS**

| | |
|---|---|
| 1897821 | 6 Meter Power Cord ( US ) |
| 1895820 | Standard Power Cord ( US ) |
| 1895821 | UK Power Cord |
| 1895822 | Continental Europe Power Cord |
| 1895823 | Japan Power Cord |

**PRASS PAIRED EMG ELECTRODES**

| | |
|---|---|
| 8227301 | 25 mm, Protected Pin, 5 Pkg/Box |
| 8227304 | 18 mm, Protected Pin, 5 Pkg/Box |

**SUBDERMAL/EEG NEEDLE ELECTRODES**

| | |
|---|---|
| 8227103 | Stainless Steel, 1.0 meter cable, 1set/Box |
| 8227411 | Paired Subdermal Electrode, Protected Pin, 4 Paired, 2 Single |

**EMG HOOKWIRE ELECTRODES**

| | |
|---|---|
| 8226326 | EMG Paired Hookwire Electrode, Protected Pin, 2 Pr/Box |
| 8226626 | EMG Single Hookwire Electrode, Protected Pin, 6/Box |

**STIMULUS-DISSECTION INSTRUMENTS**

| | |
|---|---|
| 1352400 | Stimulus Dissection Instrument Set, 1 Set |
| 1353400 | Neurotologic Stimulus-Dissection Instrument Set, 1 Set |
| 1353413 | NSD Raspatory, Wide Right, 1 Ea. |
| 1353414 | NSD Raspatory, Wide Left, 1 Ea. |
| 1352415 | Cable, Protected Pin, 1 Ea. |
| 1352396 | Sterilization Tray, 1 Ea. |

**OTHER STIMULUS-DISSECTION INSTRUMENTS**

| | |
|---|---|
| 1352408 | Sickle Knife, 5.0mm, 1 Ea. |
| 1352409 | 90º Hook, 1.0mm, 1 Ea. |
| 1352410 | Crabtree - Large 3.0mm, 1 Ea. |
| 1353406 | Neurotologic Stimulus-Dissection Round Knife, 3mm 1/Ea |

## Appendix B: Preventive and Corrective Maintenance

User maintenance for the NIM 2.0 is limited to visual inspection before use and periodic cleaning. Annual "Calibration" and "System Quick Check" w/ Simulator and System Safety Checks accurate to EN 60601-1 is recommended. **Please see Additional Precaution**

Model # _____ S/N _____ Tester _____ Date _____

### A. Calibration and System Quick Check

Medtronic Xomed recommends "Calibration" and "System Quick Check" at installation and thereafter at yearly intervals.

**1.Calibrate the screen as follows:** .....(A.1.a - h) _____( √ )

a. Turn the power OFF for at least 5 seconds, and then turn it ON again.
b. When the "Splash Screen" (with the device name and Medtronic logo) appears, press the screen until you are prompted to remove your hand by the text message *"Please remove your hand from the screen to continue"*.
c. The screen will then display two buttons, the large one at the top is labeled *"Touch Screen Calibration"* Press this button.
d. The screen will then display the text message: *"Touch the lower left of the screen"* - precisely press the lower left corner of the display screen.
e. The screen will then display the text message: *"Touch the upper right of the screen"* - precisely press the upper right corner of the display screen.
f. The screen will then display the text message: *"Press circle to verify calibration"* - precisely press the center of the circle displayed on the screen.
g. If the touch screen does not "sense" the final touch as being in the center of the displayed circle, the calibration sequence will repeat.
h. On successful completion of the calibration, the NIM will enter normal operating mode.

**2.System Quick Check w/ Simulator**.....(A.2.a - f) _____( √ )

Use Patient Simulator to confirm appropriate behavior.
Refer to the Patient Simulator User's Guide to confirm the following:

a. System Setup _____ ( √ )
b. Confirming Electrodes _____
c. Electrode Lead Off _____
d. Mechanical Stimulation _____
e. EMG Stimulating and Tones _____
f. Baseline Test _____

### B. System Safety Check

Medtronic Xomed recommends System Safety Checks to be scheduled at yearly intervals.

EN 60601-1 Safety Analysis

- In accordance with local procedures, perform a complete Safety Analysis for a Class 1, Type BF Device on the NIM Console.
- Utilize "Ground" connector found on rear of console as Chassis ground.
- For Patient Leakage and Mains on Applied Parts tests, a Patient Interface must be attached to the NIM Console with electrodes connected to each channel.
- Ensure Ground Impedance is less than 2.0 Ohms when measured with a 25 Amp source. Record in (a) below.

**1.High Potential (Hi-Pot) Testing**.....(B.1.a - d) _____( √ )

In accordance with local procedures, perform the following Hi-Pot tests on the NIM Console.

**NOTE**: Perform Test at voltages indicated and record values in space as needed.

- **Safety ground to Line/Neutral.**
  - Apply Hi-Pot to Line and Neutral of Power Inlet of NIM Console while monitoring Ground.
- **Safety ground to Patient Interface Ground.**
  - Apply Hi-Pot to Green Ground pin of Patient Interface w/ Interface connected to rear of NIM Console while monitoring Ground.
- **Safety ground to Patient Interface Stim +.**
  - Apply Hi-Pot to Stim + pin of Patient Interface w/ Interface connected to rear of NIM Console while monitoring Ground.

| | System Safety Check | Manufacturers Specifications | Recorded Value |
|---|---|---|---|
| a. | Ground impedance | <2. 0 Ohm @ 25 Amps | _____ |
| b. | Safety ground to Line/Neutral | <1.4 mA @ 1.5 KV RMS | _____ |
| c. | Safety ground to Patient Interface Ground | <1.4 mA @ 1.5 KV RMS | _____ |
| d. | Safety ground to Patient Interface Stim + | <1.4 mA @ 1.5 KV RMS | _____ |

**Perform an operational check using the Patient Simulator and the Patient Interface. Please see the NIM 2.0 and**

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